COSTS AND OUTCOMES OF SELF MANAGEMENT SUPPORT PROGRAMS FOR TYPE 2 DIABETIC PATIENTS IN BANGKOK, THAILAND.

Miss Pornpan Khwakhong

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ต้นทุนและผลลัพธ์ของรูปแบบการสนับสนุนการดูแลรักษาตนเองแบบต่างๆสำหรับผู้ป่วยเบาหวานชนิดที่ 2 ในกรุงเทพมหานคร ประเทศไทย

นางสาวพรพรรณ ขวาของ

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By	Miss Pornpan Khwakhong
Field of Study	Research for Health Development
Thesis Advisor	Associate Professor Wiroj Jiamjarasrangsi, MD., PhD
Thesis Co-advisor	Associate Professor Usa Chaikledkaew, Ph.D

Accepted by the Graduate School, Chulalongkorn University in Partial Fulfillment of the Requirements for the Doctoral Degree

…….. Dean of the Graduate School
(Associate Professor Amorn Petsom, Ph.D.)

THESIS COMMITTEE

…….. Chairman
(Assistant Professor Pongchai Harnyuttanakorn, Ph.D.)

……. Thesis Advisor
(Associate Professor Wiroj Jiamjarasrangsi, MD., PhD)

…….. Thesis Co-advisor
(Associate Professor Usa Chaikledkaew, Ph.D)

…….. Examiner
(Associate Professor Sathirakorn Pongpanich, Ph.D.)

…….. External Examiner
(Kaveepong Lertwachara,Ph.D.)

พรพรรณ ขวาของ : ต้นทุนและผลลัพธ์ของรูปแบบการสนับสนุนการดูแลรักษาตนเองแบบต่างๆสำหรับผู้ป่วยเบาหวานชนิดที่ 2 ในกรุงเทพมหานคร ประเท ศไทย. (COSTS AND OUTCOMES OF SELF MANAGEMENT SUPPORT PROGRAMS FOR TYPE 2 DIABETIC PATIENTS IN BANGKOK, THAILAND) อ. ที่ปรึกษาวิทยานิพนธ์หลัก :รศ.นพ.ดร. วิโรจน์ เจียมจรัสรังษี ,อ. ที่ปรึกษาวิทยานิพนธ์ร่วม: รศ.ภญ.ดร.อุษา ฉายเกล็ดแก้ว 110 หน้า.

การศึกษานี้มีวัตถุประสงค์ในการประเมินต้นทุน, ต้นทุนประสิทธิผล และต้นทุนอรรถประโยชน์ของโปรแกรมการสนับสนุนดูแลตนเอง 4 โปรแกรมในบริบทกรุงเทพมหานคร. การวิเคราะห์ต้นทุน 3 ชนิดประกอบด้วย 1) การวิเคราะห์ต้นทุนต่ำสุด 2) การวิเคราะห์ต้นทุนประสิทธิผล, และ 3) การวิเคราะห์ต้นทุนอรรถประโยชน์ ถูกทำไปพร้อมกับการวิจัยที่มีกลุ่มทดลองและกลุ่มควบคุมซึ่งมีเป้าหมายในการทดสอบประสิทธิผลของการสนับสนุนดูแลตนเองผ่านทางบุคคลากรทางการแพทย์, ผู้ป่วยเบาหวานที่มีศักยภาพ,ทางโทรศัพท์ และทางเวบไซต์ในผู้ป่วยเบาหวานชนิดที่ 2 ซึ่ง อายุมากกว่า 20 ปี ระดับน้ำตาลสะสมในเลือดมากกว่า 7% รักษาเบาหวานในสถานพยาบาล และ ศูนย์บริการสาธารณสุขในเขตกรุงเทพ มหานคร การวิเคราะห์ทางเศรษฐศาสตร์ทำในมุมมองผู้ให้บริการและมุมมองสังคม

โปรแกรมการสนับสนุนตนเองผ่านทางโทรศัพท์ เป็นโปรแกรมที่มีราคาถูกและ คือทางเลือกลำดับที่ 1 ในบรรดาโปรแกรมการสนับสนุนดูแลตนเอง โปรแกรมการสนับสนุนดูแลตนเองผ่าน website คือทางเลือกลำดับที่ 2 รองลงมา ส่วนโปรแกรมการสนับสนุนดูแลตนเองผ่านทางบุคลากรทางการแพทย์ คือ ทางเลือกลำดับที่ 3 ในเขตกรุงเทพมหานคร (มุมมองทางสังคม)

สาขาวิชา วิจัยเพื่อการพัฒนาสุขภาพ ลายมือชื่อนิสิต.....

ปีการศึกษา 2555 ลายมือชื่อ อ.ที่ปรึกษาวิทยานิพนธ์หลัก.....

ลายมือชื่อ อ.ที่ปรึกษาวิทยานิพนธ์ร่วม.....

#5087776120 : RESEARCH FOR HEALTH DEVELOPMENT
KEYWORDS : COST/ OUTCOME/ SELF-MANAGEMENT SUPPORT/ TYPE 2 DIABETIC PATIENTS

PORNPAN KHWAKHONG : COSTS AND OUTCOMES OF SELF MANAGEMENT SUPPORT PROGRAMS FOR TYPE 2 DIABETIC PATIENTS IN BANGKOK,THAILAND. ADVISOR : ASSOC. PROF. WIROJ JIAMJARASRANGSI, Ph.D., CO-ADVISOR : ASSOC. PROF. USA CHAIKLEDKAEW, Ph.D.,110 pp.

This study aimed to evaluate the cost, cost-effectiveness, and cost utility of four models of DM-SMS programs in Bangkok context. Three types of cost analysis including (1) Cost-minimization analysis, (2) Cost-effectiveness analysis, and; (3) Cost-utility analysis were performed in the context of four prospective alongside clinical trials that aiming to examine the effectiveness of the health professional-led, peer-led, telephone-based, and web-based DM-SMS programs among type 2 diabetic patients aged >20 years, glycated hemoglobin or HbA1c>7%, and seeking healthcare for selected hospitals and public health centers in Bangkok. These economic analyses were in both the provider and societal perspectives.

The results showed that self-management support by automatic telephone is not expensive including the first choice among self-management programs . Self-management support by website is the second choice. Finally, Self-management support by health personnel is the third choice in area of Bangkok. (societal perspective)

Field of Study: Research for Health Development Student's Signature .....
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Co-advisor's Signature .....

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CHAPTER I

INTRODUCTION

BACKGROUND AND RATIONALE:

The prevalence of type 2 diabetes in Asian populations has increased rapidly in recent decades, with a disproportionate burden among the young and middle aged. It is characterized by rapid rate of increase over short periods and onset at a relatively young age and low body mass index (Chan et al., 2009). Type 2 diabetes mellitus was previously less common in non-Western countries where the calorie consumption was lower and daily physical activity was higher. However, as more and more people in these countries adopt Western lifestyles, weight gain and type 2 diabetes mellitus are becoming virtually epidemic (Ligaray et al.,2009).

In Thailand, the Third National Health Examination survey in 2004 reported that diabetes and impaired fasting glucose (IFG) were uniformly high in all regions. Prevalence of diabetes and IFG weighted to the national 2004 population was 6.7 % (6.0% in men and 7.4 % in women) and 12.5% (14.7% in men and 10.4% in women), respectively. The disease was more common in urban compared to rural men but otherwise prevalence was relatively uniform across geographical regions (Aekplakorn et al.,2007). In 2007, numbers of diabetes patients and persons with impaired glucose tolerance in Thailand were approximately 3 and 1 millions respectively. In 2025, these figures was projected to be 4 millions diabetes and 2 millions impaired glucose tolerance cases (Chan et al.,2009).

Self-management support is one of the six critical elements of the Chronic Care Model that was developed based on available literature about chronic disease management (Naomi et al.,2007). It is considered as one of the important backbones for the care of chronic diseases including diabetes care over the past

30 years (Etzwiler, 1980 ; Etzwiler, 1986; Hiss,1986). Self-management interventions are defined as including instruction in such skills as weight loss/weight management, physical activity, and medication management and blood glucose monitoring as well as other tasks specific to diabetes management (Norris, 2001). The goal of diabetes self-management education (DSME) is therefore to help patients to take control of their own condition by improving their knowledge and skills for self-directed behavior change, enabling them to integrate self-management into their daily lives and ultimately to reduce the risk of complications (NICE, 2003).

Basing on previous researches, self-management program was delivered in many settings including in the clinic, workplace, home and the community (Madden et al., 2008). Each setting uses a variety of tactics to support self-management such as web-based interventions, individual or group counseling, group programs (group: ongoing cycle; group: formal/structured), group medical visits, community-based classes, activities or teachers and telephone follow-up(Fisher et al., 2005 ; Jordan et al., 2006).

Meta-analysis showed that diabetes self-management education is effective in helping people with diabetes control their illness and maximize their health (Norris et al., 2002 , 2002. 22 (suppl) ; Salber et al., 2008 ; Gary et al., 2003) and is generally accepted as a cost-effective strategy (Boren et al.,2009). It improved knowledge, self-management behaviors and metabolic control of the participants, and reduced their complications from diabetes (Fan et al., 2009). It was also associated with cost saving, cost-effectiveness, or positive return on investment (Boren et al.,2009). The benefits associated with education on self-management and lifestyle modification are positive and outweigh the costs associated with the intervention (Boren et al.,2009).Moreover, both the diabetes case management program(Gilmer et al., 2007) and the disease management program (Steuten et

al., 2007) were associated with cost-effective improvements in quality-adjusted life expectancy.

In Thailand, while research evidence of type 2 diabetes self-management education was scarce, its economic evaluation was virtually non-exist. (Teerawattananon et al.,2007) Whether these programs are efficient in the real world is unknown. Two previous researches regarding diabetes self-management education(Keeratiyutawong ,2005 and Wattana et al.,2007) addressed the effect of self-management programs in improving glycemic control among type 2 diabetic patients. These two studies used only one of the methods that are effective , but efficient results has not been addressed.

The present research is therefore aiming to perform the economic evaluation of self-management programs from a various settings, including the hospital and community based programs, and the internet and the interactive telephone based self management programs for type 2 diabetes patients in Bangkok Metropolitan, Thailand. It is expected that the study results will provide critical information for relevant policy makers both at the local and national levels.

Research questions:

1. What are the costs of the self-management programs (including those programs conducting in hospital and community settings, and those programs using telephone and computer)?

2. What are the outcomes of the self-management programs specifying in the research question 1?

3. What are the costs and outcomes of self-management support programs for type 2 diabetic patients in Bangkok, Thailand?

Objective:

1. To estimate costs of 4 self-management programs (including those programs conducting in hospital and community settings; and those programs using telephone and computer), comparing to those who receive usual care only.

2. To estimate outcomes of 4 self-management programs mentioned above in the Objective 1, comparing to those who receive usual care only.

3. To compare costs and outcomes of self-management support programs for type 2 diabetic patients in Bangkok, Thailand.

Hypothesis:

Self-management programs are more efficacious and efficient than usual care in improving clinical, humanistic and economic outcomes of type 2 diabetes patients living in Bangkok Metropolitan, Thailand.

Operation definition:

1.Diabetes education is a collaborative process through which people with or at risk for diabetes gain the knowledge and skills needed to modify behavior and successfully self-manage the disease and its related conditions.

2. Diabetes educators are health care professionals who focus on helping people with and at risk for diabetes and related conditions achieve behavior change goals that, in turn, lead to better clinical outcomes and improved health status.

3. Fixed or overhead costs included resources not directly associated with the number of participants involved or direct interaction with participants such as cost of counselors, project meetings, email communication etc., which were required for the success of the intervention but did not vary by the number of participants.

4. Variable costs are the costs incurred associated with the intervention-but vary in magnitude by the level of output or number of participants, such as

costs for phone calls, newsletters, and mailings, which increased as the number of participants increased.

5. Direct medical costs are preventive activity cost and treatment cost. (including treatment cost of complication and adverse drug event at ER visit, hospitalized visit, and OPD visit)

6. Direct non-medical cost is out-of-pocket costs of time lost, travel cost , and expense of preventive activity such as buying exercise equipment, clothing and services.

7. Indirect cost is morbidity cost as the day of absent from diabetes disease and complication.

8. The gross-costing method would be to identify, count and price out healthcare encounters or other healthcare units that represent some aggregate of a bundle of service items(e.g. the average cost per hospital day or average cost per hospitalization). Under this method, the same unit price is used for the bundled unit. The unit price that is used is typically based on average costs in the population.

10. The activity-based costing is a costing model that identifies activities in an organization and assigns the cost of each activity resource to all products and services according to the actual consumption.

11. Cost-minimization analysis (CMA) is procedure which is evaluated by comparing interventions based on cost alone and choosing the lowest cost intervention.

12. Cost-effectiveness analysis (CEA) is procedure which is evaluated by comparing five alternative treatments; occasionally one of the alternatives is usual care. Unidimentional outcomes or national units (such as HbA1c and life year gain) are used for the comparison with cost.

13. Cost-utility analysis (CUA) is procedure which is evaluated by comparing five alternative treatments; occasionally one of the alternatives is usual care. Two or more dimensional or composited outcomes (such as quality adjusted life year

gain) are used for the comparison with cost. This method allows for the comparison across programs.

14. Sensitivity analysis is a process through which the robustness of an economic model is assessed by examining the changes in results of the analysis when key variables are varied over a specific range.

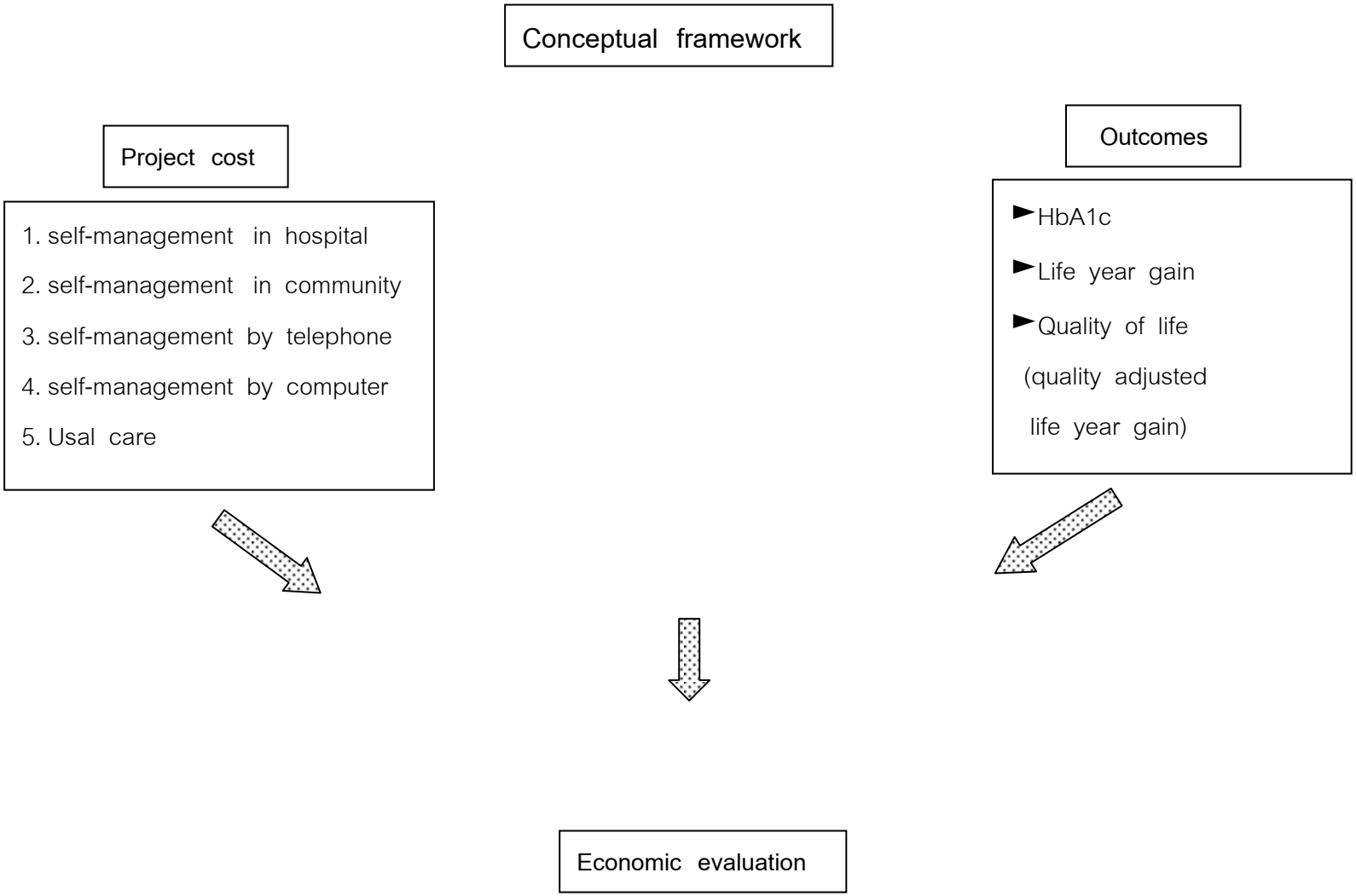


Figure 1.1 Conceptual framework

CHAPTER II

LITERATURE REVIEW

OVERVIEW

This chapter describes detailed information on the literature related to the present thesis. The topics covered include: (1) the magnitude of problem related to type 2 diabetes, (2) interventions to improve diabetes care, (3) effectiveness of diabetes self-management education, (4) type of type 2 daibetes self-management support program, (5) the Chronic Care Model, (6) resources and supports for self-management, (7) economic evaluation, (8) outcome assessment in economic evaluation, and (9) evidence about the economic evaluation of type 2 diabetes self-management support.

1) MAGNITUDE OF PROBLEM RELATED TO TYPE 2 DIABETES

Diabetes is a group of diseases marked by high blood glucose levels resulting from defects in insulin production, insulin action, or both. Type 2 diabetes accounts for about 90% to 95% of all diagnosed cases of diabetes in adults. It is related to older age, obesity, family history of diabetes, history of gestational diabetes, impaired glucose metabolism, physical inactivity, and race/ethnicity. Diabetes can affect various parts of the body and lead to serious complications including cardiovascular diseases, blindness, kidney damage, and lower-limb amputations (National diabetes fact sheet, 2007). Complications of diabetes are physiologically harmful, impact quality of life and are costly for both the patients and government (Madden et al., 2008).

The International Diabetes Federation estimated that there were 189 million people with diabetes worldwide in 2003 and the number will increase to 324 million

in 2025 (International Diabetes Federation,2006). Similarly, the World Health Organization (WHO) projected an increase from 171 million in 2000 to 366 million in 2030(Wild et al., 2004). Approximately 70% of this growth is predicted to occur in the developing region and will increasingly affect working-age population (<65 years old)(King et al.,1998). According to the United States data in 2007, almost one third of cases were undiagnosed (Ligaray et al.,2009 ; National diabetes fact sheet, 2007) .

Diabetes mellitus is one of the leading causes of morbidity and mortality which were resulting from the development of optic, renal, neuropathic, and cardiovascular disease. These complications, particularly cardiovascular disease (~50 -75% of medical expenditures), are the major sources of expenses for patients with type 2 diabetes. Approximately two thirds of type 2 diabetic patients die from heart disease or stroke. Men with diabetes face a 2-fold increased risk for coronary heart disease, and women have a 3- to 4-fold increased risk (Ligaray et al.,2009). Diabetes is the leading cause of new cases of blindness in adults aged 20 to 74 years, and it is also the leading cause of end-stage renal disease, accounting for about 40% of new cases. Neuropathy is also a major problem, affecting about 60% to 70% of people with diabetes, and more than half of lower limb amputations occur among people with diabetes (Norris et al., 2002 (1)).

Global health expenditure on diabetes and its complications was totally at least $ 232 billion in 2007(International Diabetes Federation, 2006). However, diabetes is grossly under-reported because people usually die from its complications. (Singh, 2006 : online) Complications are the main sources of all types of diabetes costs(Williams et al.,2002). The annual cost increases from $ 3220 among people without complication to $7715 for people with both micro-vascular and macro-vascular complications(Colagiuri et al., 2003).

2) INTERVENTIONS TO IMPROVE DIABETES CARE

2.1) Importance of Diabetes Self-Management Education

As lifestyle modification is likely to have favorable impact on the morbidity and mortality of diabetes, It therefore should be recommended for all people with type 2 diabetes and those at high risk for the disease(Yoon et al., 2006). When working together, people with type 2 diabetes, their support network, and their health care providers can reduce the occurrence of the diabetes complications by controlling the levels of blood glucose, blood pressure, and blood lipids, and by receiving other preventive care practices in a timely manner. (National diabetes fact sheet, 2007)

Diabetes self-management education (DSME) or Diabetes self-management training (DSMT) is the process of teaching individuals to manage their diabetes (Task Force to Revise the National Standards, 1995). It has been considered an important part of the clinical management of individuals with diabetes for more than 80 years (Bartlett,1986). Diabetes self-management training has evolved from the primarily didactic interventions in the past into the collaborative, more theoretically based “empowerment” models(Glasgow et al.,1999). Didactic interventions focusing on the acquisition of knowledge and information demonstrate positive effects on knowledge but mixed results on glycemic control and blood pressure and no effect on weight (Norris et al., 2001). Collaborative interventions focusing on knowledge tend to demonstrate positive effects on glycemic control in the short term and mixed results with follow-up of longer than 1 year. Effects of collaborative interventions on lipids, weight, and blood pressure were, however, mixed (Norris et al., 2001).

An empowered patient is one who has the knowledge, skills, attitudes and self-awareness necessary to influence their own behavior and that of others to improve the quality of their lives. Accordingly, empowerment can be seen as a

fundamental outcome of type 2 diabetes self-management education as an essential patient empowerment strategy(Funnell et al., 2004).

The American Diabetes Association recommends the annual assessment of self-management skills and knowledge of diabetes, and the provision of continuing diabetes education. (American Diabetes Association , 2001) The goals of self-management education are to optimize metabolic control, prevent acute and chronic complications, and optimize quality of life, while keeping costs acceptable(de Weerdt et al.,1989 ; NICE, 2003).

3) EFFECTIVENESS OF DIABETES SELF-MANAGEMENT EDUCATION

The value of diabetes self-management education is evident from research which suggests that patients who never received diabetes self-management education had a remarkable fourfold increased risk for major diabetes complications compared with patients who received some form of diabetes self-management education (Niccoluci et al., 1996). Most of previous studies were researched on the results of knowledge and glycemic control outcomes, while evidence on quality of life and long-term clinical outcomes was scarce.

Norris et al. conducted a systematic review of randomized controlled trials (RCTs) for the effectiveness of type 2 diabetes self-management training. Results showed that, for short-term follow-up(less than 6 months) self-management training was associated with improvements in knowledge, frequency or accuracy of blood glucose self-monitoring, self-reported dietary habits and glycemic control. Variable effects were reported for lipids, physical activity, weight and blood pressure. for longer follow-up period, interventions using regular reinforcement were sometimes more effective in improving glycemic control. Educational interventions that involved patient collaboration may be more effective than didactic interventions in improving glycemic

control, weight, and lipid profiles. The studies, however, showed no evidence of effectiveness for disease-related events or mortality (Norris et al., 2001).

Gary et al. conducted a meta-analysis of RCTs to evaluate the effects of behavioral and educational interventions on body weight and glycemic control in people with type 2 diabetes(Gary et al., 2003). The authors reported that interventions varied substantially in terms of content, frequency and setting, leadership, mode of instruction, topics, follow-up and outcomes. Nurses were most often involved in delivering the intervention (39%), followed by dieticians (26%), physicians (17%) and other professionals (13%) also reported as interventionists respectively. The main topic of most interventions was diet (70%); followed by exercise (57%), medications (35%) and self-monitoring (26%). Blood glucose levels were significantly reduced compared with controls, with the pooled effect size of -0.43 (Clark , 2008). Group and individual approaches produced comparable results. Educational interventions produced small, but non-significant, effects on weight loss (Clark , 2008).

On average, self-management education for adults with type 2 diabetes decreased glycosylated hemoglobin A1c(GHb) by 0.76% (95% CI -1.18 to – 0.34) more than the control group at immediate follow-up; by 0.26% (95% CI -0.73 to 0.21) at 1-3 months of follow-up; and by 0.26% (95% CI -0.48 to -0.05) at ≥ 4 months of follow-up. Glycosylated hemoglobin A1c (HbA1c) decreased more with additional contact time between participant and educator; a decrease of 1% was noted for every additional 23.6 hours (13.3 – 105.4) of contact (Norris et al.,2002). In addition, meta-analysis concerning the efficacy of lifestyle intervention for preventing type 2 diabetes in individuals at high risk showed that the intervention group reduced 2-hour plasma glucose by 0.84 mmol/l (95% CI 0.39-1.29) compared with the control group(Yamaoka et al., 2005). In summary, self-management education improves glycosylated hemoglobin A1c (HbA1c) levels at immediate follow-up, and increased contact time increases the effect. The benefit, however, declines 1-3 months after the intervention ceases (Norris et al.,2002).

Deakin et al. conducted a systematic review for the Cochrane Collaboration to assess the effectiveness of group-based self-management strategies for people with type 2 diabetes. Outcomes of interest were clinical, lifestyle and psychosocial, in both short-term (4-6 months) and long-term (more than a 12 months) follow-up. The review emphasized on the sessions that delivered to groups of six people or more. These covered a range of different approaches, varying in intensity, location, the person delivering the program, and whether or not family members also participated. Results showed that group-based training led to a significant short-term lowering of systolic blood pressure. It also reduced the need for diabetes medication, and significantly improved fasting blood glucose levels, glycated hemoglobin, and diabetes knowledge at both short and long-term follow-up. Improvement in self-efficacy, self-management, treatment satisfaction and quality of life (at longer term follow-up only) was also evidence. Effectiveness did not appear to depend on whether the course was delivered in primary or secondary care, who delivered it (as long as they were adequately trained) or the size of the group (Deakin et al. ,2005).

National Institute for Clinical Excellence (NICE) of the United States reported evidence for the clinical and cost effectiveness of structured patient education in type 2 diabetes care. Education was defined in terms of three main objective: (1) control of vascular risk factors; (2) management of diabetes-associated complications; and (3) quality of life. Eight studies focused on the effects of general self-management education for people with type 2 diabetes. Only three studies showed significant differences in blood glucose levels between control and intervention groups reported. The intervention in all three studies was delivered over a long period and had the shortest time between the end of the intervention and follow-up. These studies therefore provide some evidence that general self-management education can improve body mass index, medication uses, quality of life and diabetes knowledge. The other seven trials of focused self-management education in people with type 2 diabetes were reviewed. No differences were

found between the intervention and control groups for blood pressure, body mass index or weight, cholesterol or triglyceride levels. Two trials tested the combined exercise with dietary educational interventions. Both of them reported significant improvements in blood glucose levels. One of these studies also measured quality of life, which was found to be significantly improved in the intervention compared with control groups.

Two cost-effectiveness analyses were identified, both from the USA. These two studies were, however, limited in terms of their generalisability. One study reported that the behavioral intervention addressing diet and exercise was more cost-effective than the general educational intervention in adults with type 2 diabetes. The second study found that a dietary self-management program led to improvements in intermediate health outcomes in adults with type 1 and 2 diabetes, at a cost of $ 137 per person. A cost-utility analysis of the dose adjustment for normal eating (DAFNE) program was submitted to National Institute for Clinical Excellence (NICE), which reported a cost saving of £ 2679 over 10 years(NICE, 2003).

4) TYPE OF TYPE 2 DIABETES SELF-MANAGEMENT SUPPORT PROGRAM

4.1) Self-Management Support in Clinical Settings

Strong evidence exists for the prevention or delay of type 2 diabetes through lifestyle changes. Components of these programs may be adaptable for use in clinical settings (Deborah et al.,2006). In the Diabetes Prevention Program (DPP), the relative advantage of lifestyle intervention over metformin was greater in older subjects, those with lower baseline body mass index, and those with lower baseline fasting glucose (Diabetes Prevention Program Research Group,2002). Prophylactic medication clearly reduce diabetes risk; however, lifestyle changes are more effective overall and recommended as first-line strategy(American Diabetes Association ; National Institute of Diabetes, Digestive and Kidney Disease. ,2002).

Individualized counseling helped participants work toward their own goals; behavioral contracting and self-monitoring were key features, and family and social context were emphasized (Deborah et al.,2006). Relationships and social context are key factors for diabetes prevention. In these trials, close coaching relationships with study staff facilitated lifestyle change by participants. Successful diabetes prevention efforts will likely require enlisting important family members, enhancing clinician-patient relationships, practice innovations facilitating feedback to clinicians and patient follow-up, and broader societal changes supporting healthy lifestyles in the context of schools, communities, and workplaces, including vigorous follow-up may be used for subjects having less success (Deborah et al.,2006).

Cost-effectiveness analyses have shown both lifestyle and medication interventions to be beneficial, especially as they might be implemented in practice of clinical settings (Deborah et al.,2006).

4.2) Self-Management Support in Community Settings

There is some evidence suggesting that individuals with diabetes can improve their self-management skills through classes led by non-clinician peers and structured to improve the understanding of their illness and confidence or "self-efficacy" regarding self-management (Clark ,2008). From a systematic review (Norris et al.,2002(2)), data on glycemic control provide sufficient evidence that self-management education is effective in community gathering places for adults with type 2 diabetes and in the home for adolescents with type 1 diabetes. (DSME in community) In the United Kingdom(UK), the "Expert Patient Programs", based on the work of Lorig, are lay-led and focus on areas such as developing individuals' confidence to access services. (Department of Health, The Expert Patient, 2001) Ongoing research is evaluating the impact of this intervention on diabetes treatment outcomes in the United Kingdom(UK) but evaluations in the United

Kingdom(UK) and the United states (US) indicate that it produces lasting reductions in symptoms, physician visits, and costs relative to patients receiving usual care (Lorig et al., 1999; Barlow et al.,2000). Community-based groups such as these may be particularly important in settings where diabetes patients have difficulty accessing care within traditional health care settings (Clark ,2008).

4.3) Self-Management Support via Health Technologies

Telemedicine interventions for diabetes management can range from very simple systems where patients and clinicians communicate by phone, email or short message service (SMS) to complex web interfaces. Patients will typically upload home meter data and may enter other pertinent data such as anti-hyperglycemic regimens, dietary habits, activity level, and medical history (Azar et al.,2009). Providers (physicians or nurses) then review this data and provide feedback regarding medication adjustments and lifestyle modification guidelines (Azar et al.,2009).

Some available telemedicine systems include telephone assistance systems where patients will periodically receive phone calls from their clinician to help to adjust their regimen and/or other counseling (Bellazzi et al. , 2002) Others, labeled as “visit by visit systems”, provide feedback at each clinical encounter rather than between visit care. Patients upload glucometer data from home, but will wait to get feedback at the visit with their provider (Azar et al.,2009).

There are as well complete assistance systems. These systems provide day-by-day assistance to patients on therapeutic adjustments, diet and exercise. These systems include a built-in “patient unit”(Bellazzi et al.,2002) as well as a “provider” unit. However, these systems are complex, costly and often require extensive user training, These are beyond the scope of this discussion, which will

focus on web-based blood glucose upload followed by provider feedback, either by email and/or phone (Azar et al.,2009).

Telemedicine for type 2 diabetics had decreased glucose variability (Cho et al.,2006) and/or decreased 2-hour post-prandial blood glucose with the intervention (Hee-Sung K ,2007; Kim et al., 2007).

Telemedicine offers the opportunity for significant cost savings. From patients' perspective, these include travel time and lost work time for appointments. From clinicians' perspective, well-presented glucose upload data can facilitate analysis and treatment decisions while freeing up time to ultimately improve access to care. However, reimbursement for services will be a critical aspect to consider (Azar et al.,2009).

Biermann et al. found that cost saving consisted mostly of saved travel expenses and days off work. Ultimately, there was no significant difference in HbA1c among groups at the end of the trial, despite a significant improvement within groups (Biermann et al., 2000). Moreover, Cho et al. reported time savings for patients in the web-based management group, mostly in travel time, and office consult and time waiting in the office(Cho et al., 2006).

The impact of these interventions on provider's time has generally not been beneficial. In Montori's study, clinicians' time spent in reviewing data and providing feedback to patients was higher (Montori et al.,2004) while Bergenstal showed no significant time saving for the healthcare provider by reviewing web-based patient data, in comparison to usual care in which data was provided by phone (Bergenstal et al. ,2005).

There are some obstacles in the dissemination of these interventions including:

1) One major issue seems to be developing computer skills in older

computer naïve patients. Potential barriers include motor dexterity (mouse and keyboard manipulation), faulty computer skills. Overall, patients with greater dexterity and literacy to far better (Pevzner et al., 2005).

2) Patients who did not have internet access or did not know how to use the internet were often excludes from the trial. Enrolled patients had to be familiar with internet use at baseline to be eligible.

3) Architectural and technical issues such as security, privacy and confidentiality as well as ease of use. Data transfer was an issue in <5% of transfers in one study (Biermann et al., 2000), and was generally solved by simply repeating the transfer.

4) Different glucometer brands have each their own downloading software programs, which are not compatible with each other.

5) Non-adherence with data uploads were reported as a cause for dropout, as well as not showing up to clinic appointments. Therefore, motivation and straightforwardness are key elements for the success of telemedicine support.

6) There is no mechanism to reimburse physicians for non-face-to-face services.

7) Fee sharing among physicians and web administrators which will have to be defined specifically to avoid conflicts (Wojcicki J M, 2005).

8) The potential cost savings to employers from employee absenteeism are likely to drive reimbursement opportunities.

Telemedicine can be a useful tool to provide diabetes care and represents a potential solution for long distances and provider shortage. It cannot replace patient visit and direct interaction with providers, but it can supplement between-visit care and improve 'velocity to goal' –the speed of attainment of adequate metabolic control by the patient. Telemedicine can also potentially save time and travel expenses for patients (Biermann et al., 2000; Chase et al.,2003 ; Cho et al., 2006).

4.3.1) Self-management support by telephone

Telephone care can be a vital link between patients and their health care providers for ongoing self-management support, especially when patients experience difficulty accessing face-to-face services(Clark , 2008). Self-management support provided through regular telephone follow-up improves diabetes patients' outcomes. In one study among elderly type 2 men(Lorig et al., 1999), monthly calls by a nurse educator improved glycemic control, and a more recent study had similar results (Piette, 2000). These studies are consistent with the broader literature on telephone care, showing that telephone calls can improve the health of chronically ill patients (Weinberger et al. ,1989; Wasson et al ,1992) and may even serve as an effective alternative to face-to-face consultations(Clark et al., 2004).

Automated telephone calls can extend the reach of self-management education when staffing is limited or patients need frequent monitoring and behavior change supports. (Clark , 2008) Automated telephone systems can allow for frequent follow-up with patients who have difficulty accessing clinic-based services or who lack the computer supports necessary for more "high-tech" interventions. (Clark , 2008) Chronically ill patients can provide valid and reliable information using their touchtone telephone during automated monitoring calls (Clark , 2008). Piette (Piette, 1997,2000) found that low-income English- and Spanish-speaking diabetes patients receiving bi-weekly automated calls with telephone nurse follow-up responded to the calls consistently over the 12-month study period, the intervention improved patients' blood glucose self-monitoring, foot care, weight self-monitoring, and medication adherence(Piette ,2000). The study also found improvements in patients' glucose control, diabetes-related symptoms, and symptoms of depression (Clark, 2008).

4.3.2) Self-management support via Internet

Internet-based diabetes self-care support has the potential to reach large numbers of people with little extra cost, and even computer novices are willing to use Internet-based diabetes education programs(Feil et al., 2000 ; Zrebiec et al., 2001). Such systems can enhance the educational experience by using audio and video and are potentially available 24 hours per day (Clark, 2008). Internet-based diabetes supports also can allow patients to communicate with their clinicians, experts in self-care, or one another (Clark, 2008).

One of the most definitive studies of Internet-based diabetes supports (Mckay et al., 2001) evaluated a web-based self-management program. At follow-up, both patients using the website and comparison-group patients improved in their self-reported physical activity levels, however there were no significant differences between the two groups. Intervention patients who used the system more frequently reported greater change in physical activity than those who used it less often (Clark, 2008).

Murray et al.(Murray et al., 2005) conducted a Cochrane systematic review to assess the effects of interactive health communication applications (ICHAs) for people with chronic disease (Murray et al., 2005). ICHAs were described as "computer-based, usually web-based, packages for patients that combine health information with at least one of social support, decision support, or behavior change support." ICHAs were found to improve knowledge, social support, health behaviors and clinical outcomes. There was insufficient data to determine impact on emotional outcomes or cost-effectiveness. Results indicated probable positive effects on self-efficacy, but more data is needed to clarify this (Clark, 2008).

5) **THE CHRONIC CARE MODEL** (Kubina et al., 2007)

The Chronic Care Model was first developed by staff at the MacColl Institute for HealthCare Innovation in the United States base on available literature about chronic disease management. The model has been tested nationally across different health care settings, creating the national program, Improving Chronic Illness Care(ICIC).

The Chronic Care Model identifies six critical elements to deliver best practice chronic disease care. It combines the principles of health promotion and community engagement with evidence based guidelines, decision tools for health professionals and self-management support for people and their families.

There are six elements of Chronic Care Model including:

(1) Self-management support: Empower and prepare people to manage their health and health care.

Effective self-management is very different from giving people instruction. Rather it acknowledges the central role people have in determining their care, and foster in people a sense of responsibility for their own health.

(2) Delivery system design: Assure the delivery of effective, efficient clinical care and self-management.

The delivery of chronic disease care requires us to determine what care is needed, and matching roles and tasks to ensure the person gets the care they need. All team members will need centralized, up-to-date information about each person and make follow-up a part of standard procedure.

(3) Decision support: Promote clinical care that is consistent with scientific evidence and people's preferences.

Treatment decisions need to be based on proven guidelines. Health care agencies need to integrate guidelines into the day-to-day practice of health professionals in an accessible and easy-to-use manner.

(4) Clinical information system: Organize individual and population data to facilitate efficient and effective care.

A registry is an information system that can track individuals as well as populations of people. It is a necessity when managing chronic illness or preventive care.

(5) Health care organization: Create a culture, organization and mechanism that promotes safe, high quality care.

Health care systems need to create an environment in which organized efforts to improve the care of people with chronic disease takes hold and flourishes.

(6) Community resources and policies: Mobilize community resources to meet the needs of people.

6) RESOURCES AND SUPPORTS FOR SELF-MANAGEMENT(RSSM) (Edwin et al,2005)

These include services delivered at the individual level as well as supports and access to resources at the level of family, community, and policy. RSSM include the following: (Edwin et al.,2005)

(1) Individualized assessment, including consideration of cultural perspectives and other characteristics of individuals' lives that may frame self-management.

(2) Collaborative goal setting, including emphasis on specific plans for self-management that are developed with the individual.

(3) Skills for self-management, including disease-specific skills (e.g., self-monitoring of blood sugar and medication management) and more general skills, such as those related to healthy diet, physical activity, weight management, problem solving, healthy coping, and cultivating healthy relationships.

(4) Ongoing follow-up and support, including social support, motivation, and encouragement of healthy behaviors. Ongoing follow-up and support are critical predictors of both maintenance of behavior as well as clinical improvements in health promotion programs.

(5) Community resource, including safe, accessible, and affordable opportunities for physical activity, convenient and affordable sources of healthy food, and supplies needed for diabetes management, such as for blood glucose monitoring. Community linkages and coordination among providers of services and resources are important facilitators of access to resources.

(6) Continuity of quality clinical care, including having a regular source of primary care, planned visits, and routine laboratory visits for monitoring with providers who are patient centered and provider linkages to supportive services that facilitate patient self-management.

7) ECONOMIC EVALUATION (Drummond et al., 2005).

Economic evaluation is defined as the comparative analysis of alternative courses of action in terms of both their costs and consequences. There are two features characterize economic analysis including:

1) It deals with both the inputs and outputs, sometimes called costs and consequences, of activities.

2) Economic analysis concerns itself with choices. Because of scare resources, economic analysis seeks to identify and to make explicit one set of criteria that may be useful in deciding among different uses.

The basic tasks of any economic evaluation are identify, measure, value, and compare the costs and consequences of the alternatives being considered.

7.1) Cost-Minimization Analysis (CMA)

Cost-minimization is used to describe the situation where the consequences of two or more treatments or programs are broadly equivalent, so the difference between them reduces to a comparison of costs (Drummond et al., 2005).

Cost-minimization analysis is a method of calculating drug costs to project the least costly drug or therapeutic modality. Cost minimization also reflects the cost of preparing and administering a dose. This method of cost evaluation is the one used most often in evaluating the cost of a specific drug. Cost minimization can only be used to compare two products that have been shown to be equivalent in dose and therapeutic effect. Therefore, this method is most useful for comparing generic and therapeutic equivalents or «me too» drugs. In many cases, there is no reliable equivalence between two products and if therapeutic equivalence cannot be demonstrated, then cost-minimization analysis is inappropriate.(Singh, 2012 :Online)

7.2) Cost-Effectiveness Analysis (CEA) (Drummond et al., 2005)

Cost-effectiveness estimates relationship between cost with a single, common effect that may differ in magnitude between the alternative programs. A number of studies compare the cost-effectiveness of actions that do not produce health effects directly, but that achieve other clinical objectives that can be clearly linked to improvements in patient outcome. In addition, it is of most use in

situations where a decision-maker, operating with a given budget, is considering a limited range of options within a given field.

Some published literatures estimate cost-effectiveness by using final outcome, such as life-years gained or episode-free days, and others are expressed as intermediate outcomes, such as percentage cholesterol reduction or cases detected. Intermediate outputs are admissible, although care must be taken to establish a link between these and a final health output, or to show that the intermediate outputs themselves have some value. In general though, one should choose an effectiveness measure relating to a final output.

This is often true of the literature on prevention, mainly because studies to estimate an improvement in final endpoints are costly and time consuming to conduct. Here, apart from conducting the CEA using the intermediate endpoint, the only option for the economic analyst is to establish a link with a final outcome. However, when undertaking a CEA using effectiveness data relating to an intermediate endpoint the economic analyst should either (1) make a case for the intermediate endpoint having value or clinical relevance in its own right, (2) be confident that the link between intermediate and final outcomes has been adequately established by previous research, or (3) ensure that any uncertainty surrounding the link is adequately characterized in the economic study.

In CEA, the incremental cost of a program from a particular viewpoint is compared to the incremental health effects of the program, where the health effects are measured in natural units related to the objective of the program. The results are usually expressed as a cost per unit of effect.

In cost-effectiveness analysis the outcomes are measured in program-specific units. Typically the main outcome is designated as the primary effectiveness measure and used as the denominator in the cost/effectiveness ratio. There are four problems:

1) Because the measure of primary effectiveness may differ from program to program, cost-effectiveness analysis cannot be used to make comparisons across a broad set of interventions.

2) Decision-makers with a limited budget must not only determine if a new program is cost-effective but must also determine which program to reduce to free up funds for the new program. Cost-effectiveness analysis cannot typically address this issue of the opportunity cost of funding the new program.

3) In any one program there is often more than one outcome of interest.

4) Some outcomes are more important, or more valued, than others.

7.3) Cost-Utility Analysis (CUA) (Drummond et al., 2005)

Cost-utility analysis is analysis that employs utility as a measure of the value of program effect. The result of CUA is typically expressed in term of the cost per healthy year or cost per quality-adjusted life-year gained by undertaking one program instead of another. Utility is a broader measure of the benefits of health care programs.

Cost-utility analysis (CUA) is a form of evaluation that focuses particular attention on the quality of the health outcome produced or forgone by health programs or treatments. In CUA, the incremental cost of a program from a particular viewpoint is compared to the incremental health improvement attributable to the program, where the health improvement is measured in quality-adjusted life-years(QALYs) gained. The results are expressed as a cost per QALY gained.

Cost-utility analysis provides a method through which the various disparate outcomes can be combined into a single composite summary outcome. This allows broad comparisons across widely differing programs. And, finally, cost-

utility analysis provides a method to attach values to the outcomes so the more important outcomes are weighted more heavily.

Situations or circumstance for using cost-utility analysis (Drummond et al., 2005) include:

1) When health-related quality of life is the important outcome. For example, in comparing alternative programs for the treatment of arthritis, no program is expected to have an impact on mortality, and the interest is focused on how well the different programs improve the patient's physical function, social function, and psychological well-being.

2) When health-related quality of life is an important outcome. For example, evaluating neonatal intensive care for very-low-birth-weight infants, not only is survival an important outcome, but also the quality of that survival is critical.

3) When the program affects both morbidity and mortality and it is wished to have a common unit of outcome that combines both effects.

4) When the programs being compared have a wide range of different kinds of outcomes and it is wished to have a common unit of output for comparison.

5) When it is wished to compare a program to others that have already been evaluated using CUA.

6) When it is being dealt with a limited budget situation.

7) When objective is to allocate limited resources optimally by considering all alternatives and using constrained optimization to maximize the health gain achieved.

8) OUTCOME ASSESSMENT (HITAP, 2009)

There are 3 types of outcomes used in health economic evaluation:

8.1) Clinical Outcome (in natural unit)

8.1.1) Efficacy

A clinical outcome derived from patients' use of pharmaceutical product or health technology, typically randomized control trial phase 3, main concern is validity

8.1.2) Effectiveness

how well a treatment or health technology performs under real world conditions outside the context of a randomized trial where the experiment no longer hold. Main concern is generalizability or transferability

8.1.3) Intermediate/ surrogate outcome

A surrogate outcome is defined as " a laboratory measurement or a physical sign used as a substitute for a clinical meaningful end point that measures directly how a patient feels, functions or survives" e.g. blood pressure (BP) for coronary heart disease (CHD) and stroke, serum cholesterol for CHD, bone density for hip fracture

8.2) Humanistic Outcome (in common unit)

8.2.1) Quality Adjusted Life Years (QALYs)

QALY is defined as 'a year of healthy life lived' or a year of life adjusted for its quality or its value. A year in perfect health is considered equal to 1.0 QALY. The value of a year in ill health would be discounted. For example, a year bedridden might have a value equal to 0.5 QALY. The calculating formula is:

QALY = quantity(life years gained) + quality (e.g. pain-reduction, less side effect)
QALYs = number of years lived x utility

The valuation techniques for the utility are:

1) Single (comprehensive) measurement : Visual Analogue Scale, Standard Gamble, Time Trade-Off

2) Multi-attribute utility measurement : EuroQOL (EQ-5D), Health Utility Index(HUI), Quality of Well-being(QWB),Short Form 6D (SF-6D)

The EQ-5D: (Drummond et al. 2005) consists of five attributes: mobility, self-care, usual activity, pain/discomfort, and anxiety/depression (Essink-bot et al. ,1993; Brooks, 1996; Kind, 1996). Each attribute has three levels: no problem, some problems, and major problems, thus defining 243 possible health states, to which has been added 'unconscious' and 'dead' for a total of 245 in all. Preferences for the scoring function were measured with the time trade-off (TTO) technique on a random sample of approximately 3000 members of the adult population of the UK (Dolan et al., 1995, 1996b). The scoring function was developed using econometric modeling as opposed to multi-attribute utility theory. The scores fall on the 0.0 (dead) to 1.0 (perfect health) value scale.

8.2.2) Disability Adjusted Life Years (DALYs) (years of healthy life lost)

The disability-adjusted life year (DALY) is a measure of overall disease burden, expressed as the number of years lost due to ill-health, disability or early death. It captures the impact of both morbidity and mortality in a common unit of measurement. In addition, it was developed primarily to compare relative burdens among different diseases and among different populations. Ultimately, it measures disease impact rather than measuring impact of the interventions to improve health.

8.3) Economic Outcome:

There are three general approaches to the monetary valuation of health outcomes: (1) Human capital approach, **(2)** Revealed preference, and (3) Willingness to pay method. As these methods were not utilized in this research, their details were thus omitted.

9) EVIDENCE ABOUT ECONOMIC EVALUATION OF TYPE 2 DIABETES SELF-MANAGEMENT SUPPORT

Increasing numbers of published articles relating to the economic evaluation of type 2 diabetes self-management support is presently accumulating. These included both the original and review articles, and topics covered various forms of self-management programs including healthcare-based, community-based, and technology-based self-management support programs. This section presented 9 original and 2 review articles relating to self-management support for type 2 diabetic patients which were publish from 2000 to the present time. The articles were arranged according to the year of publication from the remote year to the present.

Evidence from original articles

Banister et al conducted a study to assess the effectiveness of a diabetes self-management training (DSMT) program at a community clinic in the US. Education and a glucometer were provided to 70 type 2 diabetic patients in a 4-hour class, followed by individual dietitian consults and monthly support meetings. After 2 to 12 months of program, mean HbA1C improved from 9.7 ± 2.4% to 8.2 ± 2.0% (*P*_.001) and 61% experienced positive medication outcomes. The cost of community clinic DSMT was approximately $280 per person per year, with the estimate of $185 for each point reduction in HbA1C. The authors claimed that their study indicated that community clinic DSMT can improve glycemic control at modest cost (Banister et al ,,2004).

In determining the financial and clinical benefits of implementing information technology (IT)-enabled disease management systems, Bu et al created a computer model to project the impact of IT-enabled disease management on care processes, clinical outcomes, and medical costs for patients with type 2 diabetes in the US. Several ITs modeled were examined. The authors reported that all forms of IT-enabled disease management improved the health of patients with diabetes and reduced health care expenditures. In details, over 10 years, the amount of saving for diabetes registries, computerized decision support, payer-centered technologies, remote monitoring, self-management, and integrated provider-patient systems were $14.5 billion, $10.7 billion,

$7.10 billion, $326 million, $285 million, and $16.9 billion respectively. The authors concluded that provider centered technologies such as diabetes registries currently show the most potential for benefit, and fully integrated provider-patient systems would have even greater potential for benefit. These benefits, however, must be weighed against the implementation costs (Middleton ,2007).

In evaluating the cost-effectiveness of an automated telephone self-management support with nurse care management (ATSM) intervention for patients with type 2 diabetes, Handley et al performed cost analyses in the context of a randomized trial among primary care patients comparing the effects of ATSM (n = 112) and usual care (n = 114) on diabetes-related outcomes in 4 San Francisco safety net clinics. The authors reported that the annual cost of the ATSM intervention per QALY gained, relative to usual care, was $65,167 and $32,333 for start-up and ongoing implementation costs combined and for ongoing implementation costs alone respectively. The per-patient cost to achieve a 10% increase in the proportion of intervention patients meeting American Diabetes Association exercise guidelines was estimated to be $558 when all costs were considered and $277 when only ongoing costs were considered. The authors concluded that the ATSM intervention had a cost utility for functional outcomes similar to that of many other accepted interventions, and achieved public health physical activity objectives at modest costs. As a considerable proportion of costs were fixed, cost-utility and cost-effectiveness estimates would therefore likely be substantially improved in a scaled-up ATSM program (Handley et al., 2008).

In examining the impact of diabetes self-management education/training (DSME/T) on financial outcomes (cost of patient care), Duncan et al used administrative claims data to compare process measures and costs of patients who participate and dot participate in diabetes education. The authors reported that patients participating in diabetes education have lower average costs than patients who do not participate in diabetes education, but physicians exhibit high variation in their referral rates to diabetes education. The authors concluded that the collaboration between diabetes

educators and physicians yields positive clinical quality and cost savings. They also suggested increasing referral rates to diabetes education among low-referring physicians, specifically among men and people in disadvantaged areas (Duncan et al., 2009).

Brownson et al conducted a study to estimate the cost-effectiveness of diabetes self-management programs in real-world community primary care settings. The clinical results and costs were based on programs of the Diabetes Initiative of the Robert Wood Johnson Foundation, which were implemented in primary care and community settings. A Markov simulation model was utilized to estimate the long-term effects of self-management interventions in a health systems perspective. The results showed that the intervention does reduce discounted lifetime treatment and complication costs by $3,385, but this is more than offset by the $15,031 cost of implementing the intervention and maintaining its effects in subsequent years. The incremental cost-effectiveness ratio is $39 563/QALY, well below a common benchmark of $50 000/QALY. The authors concluded that the model generally predicts acceptable cost-effectiveness ratios, and self-management programs for type 2 diabetes are cost-effective from a health systems perspective. These findings may therefore justify increased reimbursement for effective self-management programs in diverse settings (Brownson el al., 2009).

Dallosso et al conducted a study to o assess the long term clinical and cost effectiveness of the diabetes education and self management for ongoing and newly diagnosed (DESMOND) intervention compared with usual care in people with newly diagnosed type 2 diabetes in the United Kingdom. A cost-utility analysis was undertaken that used data from a 12 month, multicentre, cluster randomized controlled trial to model long term outcomes including: use of therapies, incidence of complications, mortality, and associated effect on costs and health related quality of life. Results showed that the estimated mean incremental lifetime cost per person receiving the DESMOND intervention is £209 (95% confidence interval −£704 to £1137; €251, −€844 to €1363; $326, −$1098 to $1773), the incremental gain in QALYs per person is

0.0392 (−0.0813 to 0.1786), and the mean incremental cost per QALY is £5387. Using "real world" intervention costs, the lifetime incremental cost of the DESMOND intervention is £82 (−£831 to £1010) and the mean incremental cost per QALY gained is £2092. The authors concluded that the DESMOND intervention is likely to be cost effective, with reductions in weight and smoking being the main benefits delivered. (Gillett el al.,2010).

In addition to the previous study, Duncan et al used the commercial and Medicare payer-derived claims data were used to assess the relationship between DSME/T provided by diabetes educators only and cost. The authors reported that diabetic patients who had DSMT encounters provided by diabetes educators in accredited/recognized programs are likely to show lower cost patterns when those patients without DSMT encounters. Furthermore, patients with multiple episodes of DSMT are more likely to receive care in accordance with recommended guidelines and to comply with diabetes-related prescription regimens, resulting in lower costs and utilization trends. The authors concluded that the collaboration between diabetes educators and patients continues to demonstrate positive clinical quality outcomes and cost savings. In addition, repeated DSMT encounters over time result in a dose-response effect on positive outcomes (Duncan et al., 2011).

Moran et al conducted a study to evaluate a care delivery model integrating the registered nurse–certified diabetes educator into the patient-centered medical home to assist in achieving positive clinical and cost outcomes in diabetes care. A 1-group pretest-posttest research design was used, and cost-effectiveness measures included program costs, performance incentives, revenue, provider time saved, and patient health care utilization. The authors concluded that integrating the registered nurse–certified diabetes educator in the patient-centered medical home improves clinical outcomes and is cost-effective, and diabetes education and support are integral components of diabetes management (Moran el al., 2011).

Schechter et al conducted a study to characterize the costs and cost-effectiveness of a telephonic behavioral intervention to promote glycemic control in the Improving Diabetes Outcomes study in the US. The provider perspective and a time horizon to the end of the 1-year intervention were utilized in the study. The authors reported that the intervention cost was $176.61 per person randomized to the telephone group to achieve a mean 0.36% of HbA1C improvement. The incremental cost-effectiveness ratio was $490.58 per incremental percentage point of HbA1C improvement and $2,617.35 per person over a 1-year intervention in achieving the HbA1C goal. The authors concluded that the costs of a telephonic intervention for diabetes self-management support are moderate and commensurate to the modest improvement in glycemic control. (Schechter el al., 2012).

Evidence from systematic review

Klonoff et al conducted a review of the literature to select articles that perfo rmed a cost-benefit analysis for 17 widely practiced interventions for diabetes. They reported that type 2 diabetes and self-management training was possibly cost-effective, while interventions with unclear economic impact included case management, medical nutrition therapy, self-monitoring of blood glucose, foot care, blood pressure control, blood lipid control, smoking cessation, exercise, weight loss, HbA1c measurement, influenza vaccination, and pneumococcus vaccination (Klonoff el al., 2000).

Boren et al reviewed the published literature to evaluate the economic benefits and costs associated with diabetes education. Related literatures were searched from the Medline database (1991-2006) and Google. The authors found that more than half (18) of the 26 papers reported findings that diabetes education (and disease management) was associated with decreased cost, cost saving, cost-effectiveness, or positive return on investment. They concluded that the benefits associated with education on self-management and lifestyle modification for people with diabetes are positive and outweigh the costs associated with the intervention (Boren el at., 2009).

CHAPTER III

METHODOLOGY

1. Research design

The economic evaluation was conducted in the context of the prospective alongside clinical trials that aiming to examine the effectiveness of four models of type 2 diabetes self-management support (DM-SMS) programs. In this economic evaluation, three types of cost analysis were performed including: (1) Cost-minimization analysis or CMA; (2) Cost-effectiveness analysis or CEA, and; (3) Cost-utility analysis or CUA.

The randomized controlled trials were conducted by the separated groups of investigators. However, additional data relating to the economic evaluations (such as direct medical cost, direct non-medical cost, and quality of life) were collected by the author of present thesis. The cost-minimization, cost-effectiveness and cost-utility were then analyzed by relying on cost (both direct and indirect costs) and efficacy data obtained from these four models of the DM-SMS. This cost analysis part was the main task for the author of this thesis.

The rationale behind performing these three types of cost analysis simultaneously was that, while the cost minimization analysis can provide the distinct view of cost, it does not focus on outcomes which assume the same for all the alternatives. Outcomes are therefore considered in the cost effectiveness analysis because the best alternative cannot be selected based only on the cheapest price or lowest cost. It is necessary to consider for cost and results altogether. The current research started from cost analysis to cost effectiveness analysis in the identification of the best choice for the DM-SMS program.

2. Overview of the Prospective alongside clinical trials

The aim of this component was to evaluate the efficacy of four models of type 2 diabetes self-management support (DM-SMS) programs including: (a) health professional-led, small group DM-SMS; (b) peer-led, small group DM-SMS; (c) telephone-based DM-SMS, and; (d) internet-based DM-SMS. The two-group randomized control trial was utilized in the evaluation of the efficacy of each model compared with usual care. Characteristics of the four trials corresponding to four DM-SMS programs were summarized in Table 3.1, while their details were described in Appendix c.

Table 3.1 Characteristics of the four trials corresponding to four models of type 2 diabetes self-management support (DM-SMS) programs

Characteristics	DM-SMS Model				Usual Care
	Health Professional-Led	Peer-Led	Telephone-Based	Internet-based	
Participants	Diagnosed as type 2 diabetes, aged ≥ 20 years, HbA1c level > 7% (with n the last 24 weeks), BMI > 25 kg/m^2				
Setting	KCMH, PHCs	Public health centers	KCMH, LH	KCMH, 4 BCs	Same
DM-SMS /Control (person)	88 / 86	70 / 70	112 / 112	48 / 76	
Key DM-SMS Strategies	Chronic Disease Self-Management Program	Chronic Disease Self-Management Program	Trans-theoretical model for behavior change	The Self-regulation model	no
Mode of delivery	Small group	Small group	Automatic telephone	Website & E-mail	Class
Type of facilitator(s)	Health professional	Peer supporter	Educator	Educator	Nurse
Group size	8 -10 persons	8 -10 persons	no	no	up to screen
Duration (months)	6	6	6	6	10 -15 minutes
Contact frequency (times)	First 3 months: 6 Last 3 months: 2	First 3 months: 6 Last 3 months: 2	First 3 months: 20 Last 3 months: 2	All 24 weeks	1

KCMH = King Chulalongkorn Memorial Hospital, LH = Ladkrabunk Hospital, PHCs = Public Health Centers, BCs = Business Companies

Table 3.1 Characteristics of the four trials corresponding to four models of type 2 diabetes self-management support (DM-SMS) programs (cont.)

Characteristics	DM-SMS Model				Usual Care
	Health Professional-Led	Peer-Led	Telephone-Based	Internet-based	
Content of program	Education 6 sessions (2 hrs/session) Phone call 2 times	Education 6 sessions (2 hrs/session) Phone call 2 times	Education 23 times Phone call depending on critical answer(s)	Education with take action plan all 24 weeks E-mail&SMS : all 24 weeks	Education 1 times

3. Target population:

The target population for this study is that patients with type 2 diabetes in Bangkok, Thailand.

4. Study population:

The sample were type 2 diabetes patients who participated in the four randomized controlled trials which were intend to examine the efficacies of the four models of DM-SMS mentioning above in Table 3.1.

5. Comparator:

The model which was used as the comparison group was the model that provides knowledge to type 2 diabetes patients via pamphlets and paper documents, which are generally available in all healthcare facilities. According to this model, patients who were just diagnosed as having type 2 diabetes and/or those who have never received the diabetes-related health education will be invited to participate in the nurse-led diabetes health education for 10 to 15 minutes while waiting for the physician encounter. Pamphlets and paper documents were also distributed to the patients during this activity.

6. Time horizon:

The six months duration was used to estimate cost and outcome.

7. Perspectives:

All analyses were in the health provider and society of perspectives.

8. Discounting:

Due to the data was collected within the short period (within 1 year), discounting or reduction for costs and outcomes were therefore not applied.

9. Outcome Measurement

This study focused on both the clinical (glycemic control status) and humanistic (Quality Adjusted Life Years or QALYs) outcomes. Gllycemic control status outcome was utilized in the cost-effectiveness analysis, while QALYs was utilized in the cost-utility analysis.

Glycemic control status was indicated by the glycated hemoglobin (HbA1c) level. Each participant's HbA1c status in both the intervention and controlled group was assessed at the baseline, 3 and 6 months of the study period at the biomedical laboratory of King Chulalongkorn Memorial Hospital, and the results were reported in %.

QALYs are a measure of health outcome that integrates quality and quantity of life into a common metric are measured on a scale that ranges from 0 to 1, where 0 corresponds to death and 1 corresponds to perfect health. It was calculated from EQ-5D responses using established conversion procedures (Dolan et al. 1995, 1996b). The EQ-5D consists of five domains: mobility, self-care, usual activity, pain/discomfort, and anxiety/depression (Essink-bot et al. 1993; Brooks 1996;Kind 1996). Each domain has three levels: no problem, some problems, and major problems. It defines total 245 possible health states (including 'unconscious' and 'dead'). Preferences for the scoring function were measured with the time trade-off (TTO) technique on a random sample of the adult UK population (Dolan et al. 1995, 1996b), and the scoring function was developed using econometric modeling as opposed to multi-attribute utility theory.

10. Cost Measurement

We calculated the average cost per patient of delivering each model of the DM-SMS programs (Table 3.1). Costs for starting-up and operating each DM-SMS model were described in Table 3.2. The starting-up costs covered software, training, instrument such as computer telephone, and material cost. The operating costs for each of the intervention consisted of personnel costs; costs for contracted services; printing,

supplies, and other office costs; equipment and computing costs; and indirect costs or overhead allocations.

In this cost measurement, there were three steps of calculation:

(1) Identifying resource used (component enumeration):

This step concerned about the classification of resources and / or manufacturing processes. The type of cost used in the analysis consisted of:

Direct medical cost:

a) Treatment cost for the physician-appointed visit. This is the treatment cost at the out-patient clinic and includes routine service or overhead cost and medical services (drugs, medical supplies, and laboratory procedures). Some data were collected from the out-patient treatment activities of databases at King Chulalongkorn Memorial Hospital, Lat Krabang hospital, and one public health center of the Bangkok Metropolitan Administration (BMA).

b) Cost of the self-management support program. This includes the cost for health education and the follow-up motivation. The data were acquired from the implementation of each DM-SMS program and the activity based costing was utilized in the analysis.

Direct non-medical cost:

a) Costs relating to the physician-appointed visit at the outpatient clinic. This included the opportunity cost due to the absence from work of the patient and his/her accompanying relative(s), travel cost, overnight accommodation cost, expenditure for food and drinks, as well as the cost relating to the diabetes but incurred outside the treating hospital (treatment costs in the other hospitals, clinics, pharmacies, and the cost of food supplements). These data were obtained by the survey questionnaire.

b) Costs relating to the attendant of the DM-SMS program (for some programs only). These include the opportunity cost and travelling cost, which were previously mentioned in the activity based costing.

(2) Measuring resource use (the process tracking system):

This step concerned with the monitoring the resources used by the patients.

(3) Valuing resources:

In the calculation of the cost per case, information about the type and number of services each patient received was gathered. The number was then multiplied by the unit cost of each service type to acquire the total cost of each service type. The total cost of each service type were then summed to be the overall service cost for each patient.

Expected costs / participants = total component-specific costs / number of participants.

Data of cost in the past were adjusted by consumer price index (CPI) to be relevant to the during time of analysis(2012).

Table 3.2 Identification of cost data

Cost	Source / Data	Identification	Valuation
Direct medical cost	1. Study setting	1. Intervening activity	Cost
		1.1 Education	
		1.2 Tracking	
	2. Hospital	2. Medical services	
		2.1 Medicines	Reference price
		2.2 Medical supplies	Reference price
		2.3 Laboratory	Reimbursement
Direct- non medical cost	1. Transportation	1.1 Distance(km)	Estimate
		1.2 Carfare	Charge
	2. Food (Patient/family)	Except normal food	Price
	3. Hotel	Days of stay	Charge
	4.Time loss of patients	Hours/day	Productivity cost
	5.Time loss of caregivers	Hours/day	Productivity cost

11. Method of Economic Evaluation:

The method of the economic evaluation in present thesis included:

11.1 Cost-minimization analysis or CMA

11.2 Cost-effectiveness analysis or CEA

11.3 Cost-utility analysis or CUA

11.1) Cost-minimization analysis; CMA

This analysis compared the costs among 4 DM-SMS programs and the usual care. The purpose of this part was to deriving the incremental and minimized costs This comparison emphasized only on the cost relating to the implementation of the DM-SMS programs (process of intervention) in the societal perspective. This was due to these costs were quite different among the DM-SMS programs, while the other costs were quite similar for every patient in all programs and did not affect the overall cost. The time span for cost comparison was 6 months and the type 2 diabetes complications were not taken into account as the time span may be too short for the occurrence of long term complications.

11.2) Cost-effectiveness analysis; CEA

This analysis compared the incremental cost-effectiveness ratio in 4 DM-SMS programs for type 2 diabetes patients by using the patients who received usual care as the comparison group. Two groups of data were utilized in the analysis, namely: (1) The cost--the 6-month program costs of all 5 programs, and; (2) The outcome--HbA1c of all 5 programs. The outcome of this economic analysis was Incremental cost effectiveness ratio by the point estimate analysis, and the calculation formula is:

$$\text{Incremental cost-effectiveness ratio (ICER)} = \frac{\text{cost of DM-SMS1} - \text{cost of usual care}}{\text{HbA1c change of DM-SMS1- HbA1c change of usual care}}$$

11.3) Cost-utility analysis; CUA

This analysis compared the incremental cost-effectiveness ratio of four DM-SMS programs with the usual care. In this case, the cost-utility analysis was similar to the cost-effectiveness with the exception that the outcome was utility instead of effectiveness. This analysis contains 2 sections:

(1) The cost: analysis the overall 6-month duration cost of each SM-SMS program as well as the usual care program. The data was collected directly from each program over a period of 6 months of collecting at 5 programs.

(2) The outcome: Quality adjusted life years (QALYs).

The outcome of this part of economic analysis was the incremental cost utility ratio by the point estimate analysis, and calculation formula were as followed:

Quality adjusted life years (QALYs) = Utility * 0.5

Incremental cost-effectiveness ratio (ICER) = $\frac{\text{cost of DM-SMS1} - \text{cost of usual care}}{\text{QALYs of DM-SMS1} - \text{QALYs of usual care}}$

Utility = Preference of health condition of patients

12) Sensitivity Analysis:

This research used non-probabilistic sensitivity analysis which was therefore conducted to determine the extent of these uncertainties affect on the variation of the results.

Non-probabilistic sensitivity analysis : The one-way sensitivity analysis was used for cost-effectiveness analysis by considering variability of each parameter in the cost effectiveness ratio. The Tornado diagram was used to describe and compare the relative influence of each variable uncertainty on the variation of incremental cost effectiveness ratio(ICER) . Horizontal axis of the diagram showed the sensitivity of ICER resulting from the uncertainty of the variables(Cost, HbA1c change, and QALY) from the minimum to maximum possible values.

CHAPTER IV

RESULTS

The study results are presented in three parts. Firstly, the demographic characteristics of the study participants in each DM-SMS program, as well as in the usual care, are described. The details of cost and outcome data are then displayed. Lastly, the results of the economic evaluation of the various DM-SMS are presented.

1. Demographic characteristics of participants in 4 diabetes self-management support (DM-SMS) programs with usual care.

Overall, participants in the web-based DM-SMS program were markedly different to the other groups, particularly concerning educational level, occupation, and monthly income (Table 3.1). The educational and monthly income levels in this group were strikingly higher than the rest, and more than 60% of them are office workers or civil workers while these occupations accounted for only about 5.4-14.7 % in the other groups. They were also younger than those in usual care and health professional-led DM-SMS but comparable to the telephone-based DM-SMS groups. Their proportion of males was also higher than the other groups. However, their duration of diabetes, prevalence of co-morbidity, and distribution of marital status were quite comparable to the remaining groups.

Participants in the telephone-based DM-SMS group were also quite different from those in the other groups concerning gender composition, age, occupation, and prevalence of co-morbidity. Their proportion of male participants was higher than that in the web-based DM-SMS group but lower than those in the usual care and the health professional-led DM-SMS groups. Their proportion of labor, vendor, and agriculturist occupational group, and prevalence of co-morbidity were higher than the other groups. Their ages were younger than the usual care and the health professional-led DM-SMS

but comparable to the web-based DM-SMS groups. The overall educational level was comparable to the health-professional-led DM-SMS group but slightly higher than the usual care group and lower than the web-based DM-SMS group.

Participants in the health professional-led DM-SMS group were quite comparable to those in the usual care group concerning age, monthly income, prevalence of co-morbidity, and the distributions of gender, marital status, and occupation. Their durations of diabetes were, however, slightly longer than those in the usual care group. In addition, their educational levels were slightly higher than those of the usual care group.

In summary, while the participants in the health professional-led DM-SMS group were quite comparable to those in the usual care group, the participants in the telephone-based and web-based DM-SMS groups were markedly different from the remaining two groups in many aspects—particularly on gender composition, age, monthly income, and educational level (Table 4.1).

Table 4.1 Summary of Demographic characteristic of patients in various DM-SMS programs

Characteristics	Usual care	DM-SMS Programs		
		Professional led	Telephone based	Website based
	(n=88)	(n=86)	(n=112)	(n=76)
Gender (N ,%)				
Female	64(72.7)	66(76.7)	73(65.2)	34(43.6)
Male	24(27.3)	20(23.3)	39(34.8)	44(56.4)
Age (year)				
Mean (SD)	61.8(8.6)	62.9(10.4)	54.25(9.1)	53.59(8.6)
Marital status (N ,%)				
Married	61(69.3)	50(58.1)	80(71.4)	49(76.6)
Single/Divorce	27(30.7)	36(41.9)	32(28.6)	15(23.4)
Education (N ,%)				
- Primary school	72(81.8)	59(68.6)	71(63.4)	
- Secondary school	11(12.5)	15(17.4)	14(12.5)	13(20.3)
- > Secondary school	5(5.7)	12(14)	14(12.5)	
≥Bachelor degree			13(11.6)	51(79.7)
Occupation (N ,%)				
Labor, Vendor, Agriculturist	24(27.3)	21(21.4)	51(45.5)	8(12.5)
Officer worker, Civil worker	13(14.7)	9(10.5)	6(5.4)	39(60.9)
Retired/Housewife	51(58)	56(65.1)	52(46.4)	17(26.6)
Income(Baht/month)				
Mean (SD)	5,000(Median)	5,000(Median)	-	54,100(60,419)
Duration of DM (Year)				
Mean (SD)	7(Median)	9.5(Median)	7.8(5.8)	7.14(6.1)
Co-morbidity (N ,%)				
No	16(18.2)	17(19.8)	1(0.9)	13(20.3)
Yes	82(81.8)	69(80.3)	111(99.1)	51(79.7)

2. Cost outcome :

2.1 Cost per patient

Cost associated with self-management diabetes support was considered as the intervention cost. Education and tracking activities are the main costs of health service from provider, while the opportunity and transportation costs the main sources of patient cost (Table 4.2).

The provider's cost per patient were 33, 550, 770, 1,554 and 2,029 baht for the usual care, profession-led, peer-led, telephone-based, and web-based DM-SMS programs respectively. In societal perspective, the corresponding costs per patient for these programs were 291, 1,786, 2,006, 1,567 and 2,287 baht, respectively (Table 4.2).

In summary, among DM-SMS programs (except usual care), cost per patient was highest for the web-based DM-SMS program (2,287 baht), and lowest for the telephone based DM-SMS program (1,567 baht). Provider cost markedly affected the cost per patient of the telephone-based (99.17%) and web-based (88.72%) DM-SMS programs. The costs per patient of other programs were under the influence of patient cost (69.2% for the professional-led, 61.6% for the peer-led DM-SMS programs, and 88.6% for the usual care). Major proportions of the provider's activity costs were the education cost for almost all programs, except for the web based DM-SMS program(Table 4.2).

Table 4.2 The summary of the cost per case of various type 2 diabetes self-management support (DM-SMS) programs

Cost item (Baht)	Usual Care	DM-SMS Programs			
		Professional led	Peer led	Telephone based	Website based
Health Provider Perspective					
Educational cost	33	455	643	1,339	592
Tracking cost	0	95	126	215	1,437
Cost / person	33	550	770	1,554	2,029
[%]	[11.3]	[30.8]	[38.4]	[99.2]	[88.7]
Patients Perspective					
Opportunity cost	161	654	654	13	161
Transportation	97	582	582	0	97
Cost / person	258	1,236	1,236	13	258
[%]	[88.7]	[69.2]	[61.6]	[0.8]	[11.3]
Societal Perspective					
Cost / person	291	1,786	2,006	1,567	2,287
[%]	[100]	[100]	[100]	[100]	[100]

2.2 Fixed and variable cost

Fixed and variable costs of each provider's activity (education and tracking activity) were firstly described. Finally, total view of fixed and variable cost are enumerated. Results were shown in Table 4.3.

The total fixed costs were 0, 25,872, 22,658, 12,4895 and 13,1915 baht for the usual care, profession-led, peer-led, telephone-based and web-based DM-SMS respectively. The corresponding total fixed cost per patients for these programs were 0,

129, 324, 1,146 and 1,490 baht respectively. Variable costs were 6,593, 8,4148, 31,277, 44,430 and 59,898 baht for the usual care, professional-led, peer-led, telephone-based, and web-based DM-SMS programs respectively. In addition their corresponding variable costs per case were 33, 421, 447, 408 and 538 baht respectively.

In summary, variable cost per patient was highest for the web-based (538 Baht), and lowest for the telephone-based (408 Baht) DM-SMS programs. Fixed cost per patient was also highest for the web-based(1490 Baht), and lowest for the professional-led (129 Baht) DM-SMS programs, when comparing among the DM-SMS programs only. Fixed costs significantly affected the cost per patient of the web-based and telephone-based DM-SMS programs because their values were quite high when comparing their proportions of fixed to variable costs with those of other DM-SMS programs. Education activity of all programs (except telephone based) were not influenced by the fixed cost. In contrary, tracking activity of the telephone- based and web-based DM-SMS programs were largely influenced by the fixed cost (Table 4.3).

Table 4.3 The fixed and variable cost of various type 2 diabetes the self-management support (DM-SMS) programs

Item	Usual care	DM-SMS programs			
		Professional led	Peer led	Telephone based	Website based
Education Activity					
Fixed cost	0	20,247	18,507	111,156	32,979
Variable cost	6,593	70,742	26,585	34,772	43,911
Total cost (Baht)	6,593	90,989	45,092	145,928	76,890
Output (times)	120	120	42	2507	24
Cost per times (Baht)	55	758	1,074	58	3,204
Patient (person)	200	200	70	109	130
Cost per person(Baht)	33	455	644	1339	592
Tracking Activity					
Fixed cost	0	5,625	4,151	13,738	98,936
Variable cost	0	13,406	4,692	9,658	15,987
Total cost (Baht)	0	19,031	8,843	23,397	114,923
Output (times)	0	400	140	48	216
Cost per times (Baht)	0	48	63	487	532
Patient (person)	200	200	70	109	80
Cost per person(Baht)	0	95	126	215	1437
Overall Activity					
Total fixed cost	0	25,872	22,658	124,895	131,915
Total variable cost	6,593	84,148	31,277	44,430	59,898
Fixed cost/person (Baht)	0	129	324	1,146	1,490
Variable cost/person (Baht)	33	421	447	408	538
Cost per person (Baht)	33	550	771	1,553	2,028

2.3 Incremental cost per patient

This part considers the difference between cost per case of various DM-SMS programs with usual care. Results are displayed in Table 4.4.

Incremental costs of the professional- led, peer- led, telephone- based and web-based DM-SMS programs in societal perspective were 1,495, 1,714, 1,309, and 1,996 baht respectively. In provider perspective, these figures were 517, 736, 1,554 and 1,996 baht respectively.

In summary, when compared with the usual care, the incremental costs were the highest for the web-based (1,996 baht) and peer-led (1,714 baht) DM-SMS programs respectively, while that for the telephone-based DM-SMS was the lowest (1,309 Baht) (Table 4.4).

Table 4.4 Per patient difference in costs of the four self-management interventions relative to the usual care over six months

Cost item (Baht)	Professional led	Peer led	Telephone based	Website based
Health Provider Perspective				
Educational cost	422	610	1,339	559
Tracking cost	95	126	215	1,437
Total cost	517	736	1,554	1,996
Patients Perspective				
Opportunity cost	493	493	-148	0
Transportation	485	485	-97	0
Total cost	978	978	-245	0
Societal Perspective				
Total cost	1,495	1,714	1,309	1,996

2.4 Description of each program cost

The details of the activity cost both from the provider and the patient perspectives were displayed in Tables 4.5 – 4.9.

Cost per person of the usual care equals to 291 baht, which was derived from the education(33 baht), opportunity(161 baht), and transportation (97 baht) costs respectively(Table 4.5). Table 4.6 depicts the cost per case of the profession-led DM-SMS program which is 1,786 baht, and consists of the education (455 baht), tracking (95 baht), opportunity(654 baht) and transportation (582 baht) costs. The cost per case of the peer-led DM-SMS program is shown in Table 4.7 and equal to 2,006

baht, which is originated from the education (644 baht), follow up (126 baht), opportunity (654 baht) and transportation (582 baht) costs. Explaining in Table 4.8 is the summation of the education (1,339 baht), follow up (215 baht) and opportunity (13 baht) cost to the total of 1,567 baht , which is the cost per case of the telephone-based DM-SMS program. Table 4.9 describes cost per case of the web- based DM-SMS program (2,287 baht), which comprises the education (592 Baht) , tracking(1,437 baht) opportunity(161 baht) and transportation (97 baht) cost.

Table 4.5 Educational cost of usual care group (24 weeks)

Item	Output (times)	Quantity (persons)	Cost (Baht)	Cost (per times)	Cost (per person)
Health Provider Perspective					
Education by nurse (1 times)	120	200	6,593	55	33
Labor cost (Baht)			4,593		
Material cost (Baht)			2,000		
Patients Perspective					
Opportunity cost (Baht)	200	200	32,250		161
Transportation (Baht)	200	200	19,400		97
Societal Perspective			58,243		291

Table 4.6 Cost of type 2 diabetes self-management support program with professional led (24 weeks)

Item	Output (times)	Quantity (persons)	Cost (Baht)	Cost (per times)	Cost (per person)
Health Provider Perspective					
Education by educator	120	200	90,989	758	455
Indirect cost			20,247		
labor cost			36,742		
Material cost			4,000		
Refreshment cost			30,000		
Follow-up by phone call	400	200	19,031	48	95
Indirect cost			5,625		
labor cost			10,206		
Phone call cost			3,200		
Patient Perspective					
Opportunity cost		200	130,792		654
Transportation		200	116,400		582
Societal Perspective			357,212		1,786

Table 4.7 Cost of type 2 diabetes self-management support program with peer led (24 weeks)

Item	Output (times)	Quantity (persons)	Cost (Baht)	Cost (per times)	Cost (per person)
Health Provider Perspective					
Education by peer	42	70	37,757	1,074	644
Indirect cost			14,947		
Opportunity cost			2,258		
Material cost			1,400		
Transportation cost			8,652		
Refreshment cost			10,500		
Tracking peer by phone call	6		758		
Indirect cost			356		
Labor cost			306		
Phone call cost			96		
Tracking peer by visiting group	3		6,577		
Indirect cost			3,204		
Labor cost			2,756		
Transportation cost			618		
Follow-up by phone call	140	70	8,843	63	126
Indirect cost			4,151		
labor cost			3,572		
Phone call cost			1,120		
Patient Perspective					
Opportunity cost			45,777		654
Transportation			40,740		582
Societal perspective			140,452		2,006

Table 4.8 Cost of type 2 diabetes self-management support program with telephone based(24 weeks)

Item	Output (times)	Quantity (persons)	Cost (Baht)	Cost (per times)	Cost (per person)
Health Provider Perspective					
Education by telephone					
First course (20 times)	2,180	109	124,132	57	1,139
Indirect cost			95,170		
Telephone cost			28,962		
Second course (2 times)	218	109	10,105	46	93
Indirect cost			7,744		
Telephone cost			2,361		
Third course (1 times)	109	109	5,552	51	51
Indirect cost			4,246		
Telephone cost			1,305		
Register and pose schedule	14	109	6,140	439	56
Indirect cost			3,997		
Labor cost			2,143		
Follow-up by phone call	48	109	23,397	487	215
Indirect cost			13,738		
Labor cost			7,348		
Phone call cost			2,310		
Patient Perspective					
Opportunity cost			1,398		13
Societal Perspective			170,722		1,567

Table 4.9 Cost of type 2 diabetes self-management program with website based (24 weeks)

Item	Output (times)	Quantity (persons)	Cost (Baht)	Cost (per times)	Cost (per person)
Health Provider Perspective					
Education by website					
Email	24	130	12,852	536	99
Indirect cost			11,015		
Labor cost			1,837		
Education of operational system of website(1 times)	4	130	64,038	16,010	493
Indirect cost			21,964		
Labor cost			3,674		
Place rental			8,000		
Instrument rental			18,000		
Material cost			700		
Transportation cost			1,200		
Refreshment cost			10,500		
Reply question by educator	120	80	64,128	534	802
Indirect cost			54,943		
Labor cost			9,185		
Reply question by others	96	80	50,795	529	635
Indirect cost			43,994		
Labor cost			6,802		
Patient Perspective					
Opportunity cost			12,900		161
Transportation cost			7,760		97
Societal Perspective					2,287

2.5 Summary of Costs :

Table 4.10 shows that the category of cost consists of direct medical and direct non medical costs. Direct medical cost is considered as health provider cost and is summation of intervening cost, routine service cost, medical care cost and laboratory cost . Direct medical cost plus direct non medical cost results in the cost in societal perspective.

Costs in the health provider perspective which ordering from the highest to the lowest values are the web-based (9,858 baht), telephone-based (9,383 baht), peer-led (8,599 baht), and health professional-led (8,379 baht) DM-SMS programs respectively (Table 4.10). When adding direct non medical cost to all programs, the results are the costs in the societal perspective. These comprise 12,424 baht for the web-based, 12,237 baht for the peer-led, 11,923 baht for the health professional-led, and 11,704 baht for the telephone-based DM-SMS programs respectively.

When comparing especially among the DM-SMS programs, the professional-led and telephone-based programs are the cheapest in the health provider and the societal perspectives respectively. Not only the web-based program more expensive in the health provider prospective, but also in the societal prospective (Table 4.10).

Table 4.10 Summary of cost of the various DM-SMS programs

Cost (Baht)	Uaual care	DM-SMS programs			
		Professional led	Peer led	Telephone based	Web based
Direct Medical Cost					
Intervening cost	33	550	770	1554	2029
Routine service cost					
Mean (SD= 42.46)	2325.6	2325.6	2325.6	2325.6	2325.6
Medical care cost					
Mean (SD=337.93)	4383	4383	4383	4383	4383
Laboratory cost					
Mean (SD=44.98)	1120	1120	1120	1120	1120
Direct Non-Medical Cost					
Appointment of OPD					
Mean (SD=523.2)	2308.5	2308.5	2308.5	2308.5	2308.5
Attend to DM-SMS	258	1236	1236	13	258
Total Cost Per Case	2566.5	3544.5	3544.5	2321.5	2566.5
Health Provider Perspective	7862	8379	8599	9383	9858
Societal Perspective	10428	11923	12143	11704	12424

2.6 Summary of Outcomes :

From table 4.11 summarized outcomes at third month of various self-management programs. Health professional led and website based DM-SMS programs had significance of self-care score. HbA1c as Clinical outcome had change, significantly at 3 months in telephone based and website based DM-SMS programs. Moreover, telephone based DM-SMS had significance of self-efficacy score and Quality of life with specific diabetes mellitus.

Table 4.11 Comparison of outcomes of experimental and control group of each DM-SMS programs (at 3 months)

Items	Health led DM-SMS		T-Test	Telephone based DM-SMS		T-Test	Web based DM-SMS		T-Test
	Int.(n=86)	Con.(n=88)	P-value	Int.(n=112)	Con.(n=112)	P-value*	Int.(n=76)	Con.(n=48)	P-value*
Clinical outcome									
HbA1c ; Mean(SD)	7.8 (0.9)[a]	7.7 (1.3)[a]	>.05[b]	8.91 (1.52)	8.86 (1.65)	<0.001*	7.46 (1.67)	8.05 (1.84)	0.001*
Cholesteral ; Mean(SD)							191.63 (38.86)	188.69(45.37)	>.05
Triglyeride; Mean(SD)							131.74 (68.79)	131.52(74.40)	>.05
LDL ; Mean(SD)							105.50 (34.24)	109.23(37.02)	>.05
Systolic pressure									
Mean(SD)	135.6 (16.9)	139.7 (16.9)	>.05				132.80(12.68)	132.40(18.15)	>.05
Diastolic pressure									
Mean(SD)	75.6 (9.9)	78.2 (9.9)	>.05				80.02 (9.31)	80.47(9.63)	>.05
BMI	26.3 (4.1)	26.6 (4.2)	>.05				26.74(5.04)	28.31(4.00)	>.05

P-value* = Difference of changing mean between groups (0 and 3 month) ; a = Median(IQR), b = P-value(Median test) ; Int. = Intervention,Con. = Control

Table 4.11 Comparison of outcomes of experimental and control group of each DM-SMS programs (at 3 months) (cont.)

Items	Health led DM-SMS		T-Test	Telephone based DM-SMS		T-Test	Web based DM-SMS		T-Test
	Int.(n=86)	Con.(n=88)	P-value	Int.(n=112)	Con.(n=112)	P-value*	Int.(n=76)	Con.(n=48)	P-value*
Behavioral outcome									
Self-efficacy score	80.7(13.5)	79.4(14.6)	>.05	80.59 (12.81)	73.58(13.87)	<0.5*	83.42 (11.10)	76.52 (15.18)	>0.5
Self-care score	88.1(18.2)	79.8(18.7)	<0.5*				73.03 (16.02)	62.47 (17.62)	<0.5*
Qaulity of life (specific DM)									
Qaulity of life	60.7 (5.5)	58.9 (7.1)	>.05	57.75(5.87)	52.69 (7.07)	<0.5*	57.87(6.87)	59.05(6.42)	>.05

Table 4.12 describes the outcomes of interest in this study. Firstly, the HbA1c values at the baseline and the third month from the trials of the three DM-SMS programs were used in calculating the magnitudes of HbA1cchange. Secondly, the QALYs were derived from multiplying the utility with 0.5 . This latter outcome was later used for calculating the cost- utility ratio in the next table (Table 4.13).

In summary, HbA1c changes were 0.2, 0, 0.4, and 0.3 percent in the usual care, health profession- led, telephone-based and web-based DM-SMS programs respectively. The corresponding QALYs of these groups were 0.42, 0.43, and 0.44 respectively(Table 4.12).

Table 4.12 Summary of outcomes of the various DM-SMS programs

Item	Usual care	DM-SMS programs			
		Professional led	Peer led	Telephone based	Web based
HbA1c (%) (Mean; SD)					
At baseline	7.90(Median)	7.80(Median)		9.33(1.67)	7.74(1.66)
At 3rd month	7.70(Median)	7.80(Median)		8.91(1.52)	7.46(1.67)
HbA1c change (%)					
Mean (SD)	0.20(Median)	0(Median)		0.42(1.53)	0.28(1.18)
Utility at 3rd month					
Mean (SD)	0.80 (0.02)	0.83 (0.02)		0.85 (0.03)	0.87 (0.06)
QALYs	0.40	0.42		0.43	0.44

3. Economic evaluation of the various DM-SMS

3.1 Results from cost-effectiveness analysis:

Table 4.13 explains the results of the cost-effectiveness analysis in both the health provider and the societal perspectives. These were conducted by comparing the proportions between incremental costs and outcomes among the DM-SMS programs.

In health provider perspective

The results of the cost-effectiveness analysis by point estimation were shown in Table 4.13. When comparing the costs among three DM-SMS programs in health provider perspective, the health professional-led DM-SMS program had the lowest cost (8,379 baht), with the HbA1c change of 0% (the bad value) and Quality of life (QALYs) of 0.42. Telephone-based DM-SMS program had the second lowest cost of 9,383 baht, with the best value in the HbA1c change (0.42%) and QALYs (0.43). Finally, Web-based DM-SMS program had the highest cost of 9,858 baht, with the HbA1c change of 0.28 and the QALYs of 0.44 (the best value).

When considering the incremental cost effectiveness ratio (ICER), The telephone-based DM-SMS program had the best value of the incremental cost per HbA1c change (6,914 baht/HbA1c change 1%), followed by the web-based DM-SMS program (24,950 baht/HbA1c change 1%). On the other hand, the health professional-led DM-SMS program had the worst value of incremental cost per HbA1c change (-2,585 baht/HbA1c change 1%)(Table 4.13).

However, when considering the QALYs as the outcome, the health professional-led DM-SMS program had the best value of incremental cost per QALYs.(34,467 baht/QALYs). The incremental cost-effectiveness ratios of changing from the usual care to the web-based and telephone-based DM-SMS programs were 57,029 and 60,840 baht /QALYs respectively,

Table 4.13 Cost-effectiveness analysis of the various DM-SMS programs

Item	Usual care	DM-SMS programs			
		Professional led	Peer led	Telephone based	Web based
Health Provider Perspective					
Cost (Baht/patient)	7,862	8,379	8,599	9,383	9,858
HbA1c change (%)	0.20	0		0.42	0.28
QALYs	0.40	0.42		0.43	0.44
Incremental cost (Baht)		517	737	1521	1996
Incremental HbA1c (%)		-0.2		0.22	0.08
Incremental QALYs		0.02		0.03	0.04
Incremental cost-effective ratio (Baht/HbA1c change 1 %)		-2585		6914	24950
Incremental cost-effective ratio (Baht/QALYs)		34,467		60,840	57,029
Societal Perspective					
Cost (Baht/patient)	10,428	11,923	12,143	11,704	12,424
HbA1c change (%)	0.20	0		0.42	0.28
QALYs	0.40	0.42		0.43	0.44
Incremental cost (Baht)		1,495	1809	1,276	1,996
Incremental HbA1c (%)		-0.2		0.22	0.08
Incremental QALYs		0.02		0.03	0.04
Incremental cost-effective ratio (Baht/HbA1c change 1 %)		-7,475		5,800	24,950
Incremental cost-effective ratio (Baht/QALYs)		99,667		51,040	57,029

In Societal perspective

The results of the cost-effectiveness analysis by point estimation were shown in Table 4.13. When comparing the costs among three DM-SMS programs in societal perspective, the telephone-based DM-SMS program had the lowest cost (11,704 baht). Secondly, The health professional-led DM-SMS program had the second lowest cost of 11,923 baht. Finally, the web-based DM-SMS program had the highest cost (12,424 baht).

When considering the incremental cost effectiveness ratio (ICER), the telephone-based DM-SMS program had the best value of the incremental cost per HbA1c change (5,800 baht/ HbA1c change 1%), followed by the web-based DM-SMS program (24,950 baht/HbA1c change 1%), with the health professional-led DM-SMS program had the worst value of incremental cost per HbA1c change (-7,475 baht/HbA1c change 1%).

However, when considering the QALYs as the outcome, the telephone-based DM-SMS had the best value of incremental cost per QALYs.(51,040 baht/QALYs) The incremental cost-effectiveness ratio of changing from the usual care to the web-based and health professional-led DM-SMS programs were 57,029 and 99,667 baht /QALYs respectively,

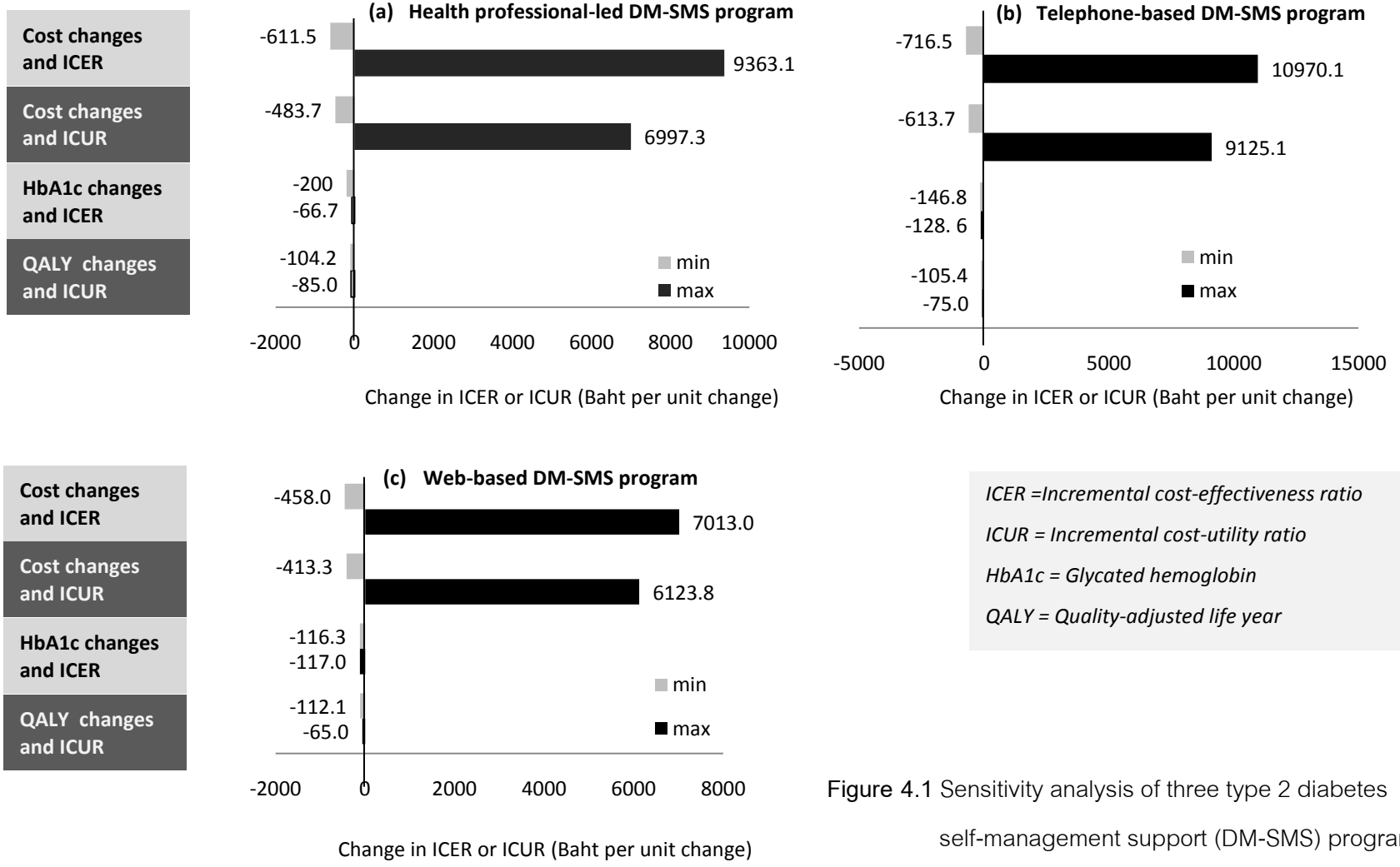
3.2 Conclusion of the cost- effectiveness analysis.

When considering the cost and outcome (HbA1c change and Quality of life) together, the telephone-based and the health professional-led DM-SMS programs had the best values of cost effectiveness and cost utility in the health provider perspective. However, only the telephone-based DM-SMS program had the best values of both cost effectiveness and cost utility in the societal perspective (Table 4.13).

3.3 Sensitivity analysis of incremental cost effectiveness ratio in societal perspective :

Sensitivity analyses were conducted to examine how changes in the values of some variables (including cost, HbA1c change and QALYs) between the minimum and maximum range affect the findings and conclusions about the incremental cost effectiveness ratio. Results were displayed by Tornado diagram in Figures 4.1(a) – (c). The longer the bar in the diagram represented the higher influence of the change in the variable value on the ICER or ICUR.

Figure 4.1 showed that—when analyzing in the societal perspective--the incremental cost effectiveness ratio(ICER) and incremental utility ratio(ICUR) were largely affected by changes in the cost of the program, while changes in HbA1c and QALY had negligible impact on the ICER or ICUR. These were true for all DM-SMS models.



ICER =Incremental cost-effectiveness ratio

ICUR = Incremental cost-utility ratio

HbA1c = Glycated hemoglobin

QALY = Quality-adjusted life year

Figure 4.1 Sensitivity analysis of three type 2 diabetes self-management support (DM-SMS) programs

CHAPTER V
DISCUSSION

SUMMARY RESULTS

Self-management support program is not treatment, but it is the complementary of therapy process. However, this method is not only to educate diabetic patients, but It is a process to support them to apply the knowledge to take care of themselves and covers skill building in various areas including; exercise, eating, taking medication and self-care for preventing complications, because diabetes is a chronic disease that will stay with patients until death. The incidence of complications and death are faster or slower depending on their extent of self-care.

Diabetes self-management support (DM-SMS) programs should be provided , because they benefit to all diabetes patients. Education costs are relatively low when considering their beneficial consequence. The benefit is particularly great when implementing the DM-SMS programs to newly diagnosed type 2 diabetic cases (Gillett el al.,2010). There are many strategies in the delivery of diabetic knowledge, depending on the context and preference of each patient. Each strategy also has different advantages and limitations.

In summary, the lowest costs among the DM-SMS programs were the health professional-led program (8,379 baht) in health provider's prospective and the telephone-based program (11,704 baht) in societal perspective. Cost was the highest for the website-based DM-SMS program, both in the health provider's and societal of perspectives. When considering the improvement of HbA1c and Quality adjusted life year (QALYs) as the outcomes, It founded that HbA1c improvement was the largest and the lowest for the telephone-based and the health professional-led DM-SMS programs respectively, while the QALYs were the same in all DM-SMS programs.

When choosing the best among more than one alternative, firstly, each intervention is considered in term of cost and effect. The intervention is accepted when it has: (a) larger cost and effect, or; (b) smaller cost and larger effect, or; (c) not different in cost with the larger effect On the other hand, the intervention is rejected when it has: (a) larger cost and smaller effect, or; (b) fails to differ in both the cost and effect. Finally, in case of no difference in effect, the intervention is then evaluated by the cost-minimization analysis. When neither smaller cost and larger effect nor larger cost and smaller effect, it is analyzed by the cost-effectiveness analysis (Henry el al.,2007).

Applying these principles into this circumstance for choosing the best DM-SMS program, firstly the clinical and cost outcomes were considered. As the HbA1c change from the baseline to the third month was not apparent for the health professional-led DM-SMS program, this program was therefore discarded from selection list. In the next step, due to no difference in the QALYs among all DM-SMS programs, the results of the cost-effectiveness analysis were then ignored. The best program was therefore be considered by relying only on the lowest cost (cost- minimization) among the DM-SMS programs.

As a result of this, the telephone based DM-SMS was therefore considered as a good alternative in both the health provider's and societal perspectives. Because it has smaller cost (9,383 and 11,704 baht in health provider's and societal perspectives, respectively) and larger effect (HbA1c change ; 0.42) than the other DM-SMS programs. This should be adopted as the dominant intervention. HbA1c change, as the clinical outcome, was pronounced in this type of DM-SMS program. In opposite, the QALYs of all programs had a tendency to close to each other. When emphasizing on this outcome, however, it was rational to conclude that the health professional-led DM-SMS program was also a good choice when considering its lowest cost (8,379 baths) in perspective of health provider. (See appendix F)

DISCUSSION

The first alternative of the DM-SMS program for Bangkok area is the telephone-based DM-SMS program. The HbA1c improvement by this program was larger, while the cost was lower, than the website-based DM-SMS program. The extent of HbA1c improvement appeared to similar to Schechter et al's report (Schechter el al., 2012). Moreover, favorable result of the cost-utility analysis was also in line with Handley et al's study (Handley et al., 2008). When comparing among the three types of DM-SMS programs, the cost of this program was low in both the perspectives of health provider and society. But its fixed cost per person was high, which was the consequence of the investment of in software and instruments in the development phase of the program. However, the telephone-based DM-SMS program saved cost of labor and time of educator, as well as the transportation cost of patients.

The second alternative is the website-based DM-SMS program. When relying on the cost-minimization analysis, the cost of this program was the highest in both the health provider's and societal perspectives. The HbA1c improvement was less than the telephone-based DM-SMS program. This magnitude of health Improvement was similar to that reported in Middleton's study (Middleton ,2007). The improvements in both the HbA1c and knowledge were of good value. Technology-based programs tended have high investment costs at the beginning period, which was the same as Middleton's finding. This was portrayed by the high fixed cost per case. However, educator had the less role for educating participants in this type of program. Patients were the center of self-learning and self-regulation through the computer interaction during their convenient time .It has no time lost or transportation cost for those attending the program. However, patients may need orientation about how to use the program at the start of the website-based DM-SMS program.

The third alternative for the DM-SMS program in Bangkok context was the health professional-based DM-SMS program. When taking into account the QALYs in the health provider's perspective, this program was the best choice which has moderate

cost in societal perspective. However, it had no effect on the HbA1c improvement in short duration of follow-up. The moderate cost for improved glycemic control reported in our report was consistent with the finding in Banister's study (Banister et al., 2004). In addition, Norris et al also reported previously that although this type of program improved patients' knowledge, but it did not impact on good HbA1c control (Norris et al., 2001). Health provider-led DM-SMS program had low investment cost. The large proportion of expenditure was associated with the transportation and opportunity costs of patients because they had to attend group meeting about 6 times. Because health personnel play an important role in this program, health care facility thereby ought to have sufficient number of educator available for this type of program. Group meetings are usually conducted on work time. Participants also have to leave job (or be retired) to participate in the program.

Although the HbA1c was not improved in the short-term, it did not mean that the health professional-led program was ineffective. Result of long-term study showed that this program was effective in improving the HbA1c outcome (Banister et al., 2004). Moreover, previous study showed that the chronic care model implementing in community primary care settings was cost-effectiveness in perspective of health system, which is relevant to this research (Brownson el al., 2009).

Conclusion

Although each model of DM-SMS programs had both advantages and disadvantages, our economic analytical result showed that, in Bangkok context, the telephone-based DM-SMS program was the best alternative when considering both the cost and outcome. This technology-based program had less limitation. It can overcome barriers related to time lost, uses no complex instruments, and can cover wide range of type 2 diabetic patient group (e.g. young, old, high or low socio-economic status). The telephone-based DM-SMS program also has high capacity to serve large volume of the patients. Its automation can reduce health personnel's time and effort.

The website-based DM-SMS program was the second best choice. The target patient group may be limited to those with high computer skill and accessible to the computer. The website-based DM-SMS is considered as a channel that healthcare provider can link to the mass volume of type 2 diabetic patients. Similar to the telephone-based DM-SMS program, the website-based DM-SMS program can also overcome barriers related to time lost.

Finally, the health personnel-led DM-SMS program was the third choice. It has limitation about time lost for those who work. This limitation can be partly overcome by appropriate time-scheduling. The sessions of the program should be scheduled throughout the year at various times of each day to accommodate the convenient time schedule of each patient. Short program session arranged while patient(s) waiting for the physician encounter on the physician appointment date is also another creative adaptation that may suite to some patients.

STRENGTHS AND LIMITATIONS

Strengths

This economic evaluation collected the data at the same time-period of the alongside randomized controlled trials, thus ensured a certain degree of data accuracy and minimized confounding effect related to time. The main analysis focused on the intervening costs which can clearly explain the difference in costs of each type 2 DM-SMS programs. Descriptions of costs in both the health provider's and societal perspectives can provide thorough cost information for all stakeholders.

Limitations

Firstly, the characteristics of the participant group in each model of the DM-SMS programs were quite varied (e.g. the participants in the website-based DM-SMS program were in younger age-group with higher level of socio-economic status, while the participants in the health professional-led DM-SMS program were the opposite, and those in the telephone-based DM-SMS program were in between). These difference

might have had confounded the comparison results among the DM-SMS programs to a certain extent.

Secondly, because the outcomes of interest confined only to the HbA1c and QALYs, this study thus had limited opportunity to examine the economic aspects of other important health outcomes (such as improvement in health behaviors, patient's satisfaction, etc.) of the DM-SMS programs.

Lastly, as the follow-up period was relatively short (6-month duration), data related to long-term outcome (e.g. hospitalization, long-term complications) was therefore not able to be included in this economic analysis.

RECOMMENDATIONS

Suggestions for policy and implementation:

For healthcare facility, the health professional-led DM-SMS program may be the good alternative due to its lowest cost of implementation. This type of program is particularly appropriate for improving diabetes knowledge of the newly diagnosed type 2 diabetic patients. This program can provide all aspects of the necessary knowledge for life-long type 2 diabetes self-management. By emphasizing on the newly diagnosed patients, the cost-effectiveness of this program can be significantly improved. Furthermore, healthcare facility usually has health personnel to take charge for this type of program.

At the national level, implementing the telephone-based DM-SMS program may be the better alternative. This type of program can serve mass number of type 2 diabetic patients. It relies on the generally available technology and is therefore easily accessible by almost all patient groups. Although the investment cost is high at the beginning, but the society will save money regarding human resource used in the implementation of the program as well as the costs related to work time loss and transportation of patients. The

latter issue is particularly imperative for Bangkok where the traffic problem is almost always existed.

Suggestions for future research:

1. **Cost**: Short- and long-term costs might be different. Short-term cost (6-month) usually confines to the intervention and out-patient costs, while long-term cost will also cover cost relating to hospitalization and long-term complications. Future study should therefore expand the duration of data collection to better reflect more holistic aspect of cost.

2. **Outcome**: Health outcome such as the improvement of HbA1c or prevention of long-term complications might not be apparent in the short-term follow-up. For short-term economic evaluation, immediate outcomes such the improvement in diabetic knowledge, health behaviors, and satisfaction of patients should also be emphasized in future research. These outcomes tend to yield more meaningful results for short-term economic evaluation of the DM-SMS program(s).

3. **Duration**: A cost-effectiveness analysis relying on the intermediate and longer term outcomes might provide obviously different results about the efficiency and value of the DM-SMS program(s). As the analysis in longer time-frame and relying on longer term outcomes will better reflect the real pictures of the efficiency and cost-effectiveness of the DM-SMS program(s), future research should be conducted in the longer time-frame..

4. **Context of study**: The economic aspects of the DM-SMS programs may be different when implementing in the context other than Bangkok metropolitan. It is therefore requisite to conducting the economic evaluation of these programs in other context, particularly in the country-side which is the major part of the country.

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APPENDICES

APPENDIX A

แบบสอบถามต้นทุนการเจ็บป่วย การออกกำลังกาย อาหาร ของผู้ป่วยเบาหวาน

แบบสอบถามชุดนี้จัดทำขึ้นเพื่อใช้สำหรับสำรวจข้อมูลต้นทุนการเจ็บป่วย การออกกำลังกาย การรับประทานอาหารของผู้ป่วยเบาหวานระหว่างดำเนินการโปรแกรม ข้อมูลที่ได้จะนำไปใช้สำหรับงานวิจัยประเมินความคุ้มค่าทางการแพทย์โปรแกรมการสนับสนุนดูแลตนเองของผู้ป่วยเบาหวานเท่านั้น และผู้วิจัยขอรับรองว่าข้อมูลที่ทุกท่านให้มานั้นจะปกปิดเป็นความลับเป็นอย่างดีไม่นำไปเผยแพร่ให้เกิดความเสียหาย

การตอบแบบสอบถาม สำหรับส่วนที่ให้เลือกตอบทำเครื่องหมาย ✓ ลงใน ☐ ที่ตรงกับความจริง ส่วนที่ตอบโดยผู้ตอบเอง ให้เขียนข้อความที่เป็นจริงใน .....ที่เว้นว่างไว้ให้

<u>ค่าใช้จ่ายของผู้ป่วย ที่เกี่ยวข้องกับการรักษาโรคเบาหวาน</u>

1. ณ.ปัจจุบัน ท่านยังประกอบอาชีพ ทำงาน หรือไม่

☐1. ไม่ทำงาน(เช่นปลดเกษียณ) ☐2. ทำงาน ☐3. อื่นๆ…….

2. ปกติการมารับการรักษา หยุดงาน หรือ ใช้เวลานานเท่าใด (ต่อ 1 ครั้งที่มารับการรักษา)

☐1. ครึ่งวัน ☐2. 1 วัน ☐3. อื่นๆ.....

3. การเดินทางมารับการรักษา (ไป-กลับ)

☐1. รถส่วนตัว ระยะทาง.....กิโลเมตร

☐2. รถโดยสาร/รถรับจ้าง ค่าใช้จ่าย.....บาท

☐3. อื่นๆ.....

4. การมารับการรักษา จ่ายค่าที่พักค้างคืน หรือไม่

☐1. ไม่มีค่าใช้จ่าย

☐2. มีค่าใช้จ่าย จำนวนเงิน.....บาท/ครั้ง

5. การมารับการรักษา ใช้จ่ายเกี่ยวกับอาหารและเครื่องดื่ม หรือไม่

☐1. ไม่มีค่าใช้จ่าย

☐2. มีค่าใช้จ่าย จำนวนเงิน.....บาท/ครั้ง

6. ส่วนใหญ่การมารับการรักษา มีญาติมาด้วย หรือไม่

☐1. ไม่มี

☐2. มีญาติมาด้วย จำนวน.....คน หยุดงานหรือไม่

☐2.1 ไม่ได้หยุดงาน

☐2.2 หยุดงาน ครึ่งวัน

☐2.3 หยุดงาน 1 วัน

☐2.4 อื่นๆ.....

7. ท่านรับยาโรคเบาหวาน ณ สถานพยาบาลประจำ ความถี่บ่อยครั้งแค่ไหน

☐1. ทุก 1 เดือน

☐2. ทุก 2 เดือน

☐3. ทุก 3 เดือน

☐4. อื่นๆ ความถี่ทุก.....เดือน

8. ในระยะเวลา **3** เดือนที่ผ่านมา ท่านมารับบริการจาก**สถานพยาบาลประจำ**ด้วย**ภาวะแทรกซ้อนจากโรคเบาหวาน** ที่ต้องทำการรักษาเร่งด่วนที่**ห้องฉุกเฉิน** หรือ **นอนรักษาในโรงพยาบาล** หรือไม่ (ภาวะแทรกซ้อน เช่น ภาวะน้ำตาลในเลือดต่ำและเกิดหมดสติ แผลเรื้อรังที่เท้าจากเบาหวานต้องอยู่ในความดูแลของแพทย์ในสถานพยาบาล)

☐1. ไม่เคย

☐2. ห้องฉุกเฉิน 2.1 จำนวน.....ครั้ง 2.2 หยุดงานเพื่อรักษา.....วัน

☐3. นอนโรงพยาบาล จำนวน.....ครั้ง จำนวน.....วัน(ทั้งหมด) ท่านมีผู้ดูแลหรือไม่

☐3.1 ไม่มี

☐3.2 ญาติ หยุดงาน.....วัน

☐3.3 จ้างผู้ดูแล จำนวนวันที่จ้าง.....วัน

☐4. อื่นๆ.....

9. ในระยะเวลา **3** เดือนที่ผ่านมา นอกเหนือจากสถานพยาบาลประจำ ท่านใช้บริการจาก**สถานพยาบาลอื่น** หรือ ซื้อสมุนไพรและอาหารเสริม**เนื่องจากโรคเบาหวาน** ณ สถานพยาบาลอื่นต่อไปนี้หรือไม่

9.1 สถานพยาบาลอื่น

☐1. ไม่เคย

☐2. เคย

2.1 สาเหตุการใช้บริการ..... 2.2 จำนวนครั้งที่ใช้บริการ.....ครั้ง/วันนอน

2.3 ค่าใช้จ่าย ต่อ ครั้ง.....บาท

9.2 คลินิก

☐1. ไม่เคย

☐2. เคย

2.1สาเหตุการใช้บริการ..... 2.2 จำนวนครั้งที่ใช้บริการ.....ครั้ง

2.3 ค่าใช้จ่าย ต่อ ครั้ง.....บาท

9.3 ร้านขายยา

☐1.ไม่เคย

☐2. เคย

2.1 สาเหตุการใช้บริการ..... 2.2จำนวนครั้งที่ใช้บริการ.....ครั้ง

2.3 ค่าใช้จ่าย ต่อ ครั้ง.....บาท

9.4 อาหารเสริม และ สมุนไพร

☐1.ไม่เคย

☐2. เคย

2.1 สาเหตุการซื้อใช้..... 2.2จำนวนครั้งที่ซื้อใช้.....ครั้ง

2.3 ค่าใช้จ่าย ต่อ ครั้ง.....บาท

10. ในระยะเวลา **3** เดือนที่ผ่านมา ท่านได้ซื้ออุปกรณ์ต่อไปนี้ เพื่อตรวจติดตามระดับน้ำหนักตัว, ระดับความดันโลหิต และระดับน้ำตาลหรือไม่

10.1 เครื่องชั่งน้ำหนัก

☐1. ไม่ได้ซื้อ

☐2. ซื้อ ค่าใช้จ่าย.....บาท

10.2 เครื่องวัดความดัน

☐1. ไม่ได้ซื้อ

☐2. ซื้อ ค่าใช้จ่าย.....บาท

10.3 เครื่องวัดระดับน้ำตาลในเลือด

☐1. ไม่ได้ซื้อ

☐2. ซื้อ ค่าใช้จ่าย.....บาท

<u>ค่าใช้จ่ายของผู้ป่วย ที่เกี่ยวข้องกับการออกกำลังกาย</u>

เมื่อท่านได้เข้าร่วมโปรแกรมสนับสนุนดูแลตนเองผู้ป่วยเบาหวาน ในระยะเวลา **3** เดือนที่ผ่านมา การออกกำลังกายของท่าน เป็นเช่นไรดังต่อไปนี้

1. ประเภทกีฬา หรือ การออกกำลังกาย

☐1. สามารถทำได้ด้วยตนเอง

☐2. ต้องทำร่วมกันเป็นหมู่คณะ

☐3. อื่นๆ.....

2. สถานที่ในการออกกำลังกาย

☐1. ที่บ้าน

☐2. ที่สาธารณะ

2.1 ความถี่ในการใช้สถานที่ ใน 1 เดือน.....ครั้ง

2.2 ค่าใช้จ่ายในการเดินทาง (ไป-กลับ).....บาท(เดินทางโดยรถประจำทาง/รับจ้าง)

2.3 ระยะทางในการเดินทาง(ไป-กลับ).....บาท(เดินทางโดยรถยนต์ส่วนตัว)

2.4 อื่นๆ.....

(หมายเหตุ - การเดินทาง (ไป-กลับ) หมายถึง บ้าน-สถานที่ออกกำลังกาย)

☐3. สถานที่เอกชน

3.1 ชำระค่าสมาชิก หรือ ค่าบริการ ○รายครั้ง ○รายเดือน ○รายปี จำนวน.....บาท

3.2 ความถี่ในการใช้สถานที่ ใน 1 เดือน.....ครั้ง

3.3 ค่าใช้จ่ายในการเดินทาง (ไป-กลับ).....บาท(เดินทางโดยรถประจำทาง/รับจ้าง)

3.4 ระยะทางในการเดินทาง(ไป-กลับ).....บาท(เดินทางโดยรถยนต์ส่วนตัว)

3.5 อื่นๆ.....

☐4. อื่นๆ.....

3. ชุด หรือ อุปกรณ์กีฬา ในระยะเวลา 3 เดือนที่ผ่านมา มีการซื้อ สำหรับการออกกำลังกายหรือไม่

☐1. ไม่ได้ซื้อ

☐2. ซื้อ ค่าใช้จ่าย.....บาท

4. การเข้าคอร์สลดน้ำหนัก หรือ ควบคุมความอ้วน ในระยะเวลา 3 เดือนที่ผ่านมา

☐1. ไม่ได้เข้าคอร์ส

☐2. เข้าคอร์ส ค่าใช้จ่าย.....บาท

<u>ค่าใช้จ่ายผู้ป่วย ที่เกี่ยวข้องกับการบริโภคอาหาร</u>

ในระยะเวลา 3 เดือนที่ผ่านมา การรับประทานอาหารของท่าน เป็นเช่นไร

1. อาหารที่รับประทานภายในบ้าน

☐1.ไม่เปลี่ยนแปลง

☐2. น้อยลง

☐3. บ่อยขึ้น

ค่าใช้จ่าย ต่อ 1 เดือน.....บาท (เฉลี่ยรวมทั้งครอบครัว)

2. อาหารที่รับประทานภายนอกบ้าน

☐1.ไม่เปลี่ยนแปลง

☐2. น้อยลง

☐3. บ่อยขึ้น

ค่าใช้จ่าย ต่อ 1 เดือน.....บาท (เฉลี่ยรวมทั้งครอบครัว)

3. อุปกรณ์การเตรียมอาหาร คู่มือการเตรียมอาหารสำหรับผู้ป่วยเบาหวาน ในระยะเวลา 3 เดือนที่ผ่านมา ท่านได้ซื้อหรือไม่

☐1. ไม่ได้ซื้อ

☐2. ซื้อ ค่าใช้จ่าย.....บาท

4. การเข้าคอร์สในการเรียนทำอาหารในระยะ 3 เดือนที่ผ่านมา

☐1. ไม่ได้เข้าคอร์ส

☐2. เข้าคอร์ส ค่าใช้จ่าย.....บาท

APPENDIX B

<u>แบบสอบถามคุณภาพชีวิต EuroQOL</u>

โปรดกาเครื่องหมาย × ลงในกล่อง ☐ ที่แสดงถึงภาวะทางสุขภาพของข้าพเจ้าในวันนี้ได้มากที่สุด

1. ความสามารถในการเคลื่อนไหว
   - ☐ ข้าพเจ้าไม่มีปัญหาเกี่ยวกับการเดิน
   - ☐ ข้าพเจ้ามีปัญหาเกี่ยวกับการเดินบ้าง
   - ☐ ข้าพเจ้าไม่สามารถเดินได้ จำเป็นต้องนอนอยู่บนเตียง

2. การดูแลตนเอง
   - ☐ ข้าพเจ้าไม่มีปัญหาในการดูแลร่างกายด้วยตนเอง
   - ☐ ข้าพเจ้ามีปัญหาบ้างในการใส่เสื้อผ้าหรืออาบน้ำด้วยตนเอง
   - ☐ ข้าพเจ้าไม่สามารถใส่เสื้อผ้าหรืออาบน้ำด้วยตนเอง

3. การทำกิจวัตรประจำวัน (เช่น การทำงานหาเลี้ยงชีพ, การเรียน, การทำงานบ้าน, การทำกิจกรรมกับ
   ครอบครัว, หรือ การทำงานอดิเรก)
   - ☐ สุขภาพของข้าพเจ้าไม่มีผลต่อการทำกิจวัตรประจำวันดังกล่าวข้างต้น
   - ☐ สุขภาพของข้าพเจ้ามีผลบ้างต่อการทำกิจวัตรประจำวันดังกล่าวข้างต้น
   - ☐ สุขภาพของข้าพเจ้ามีผลทำให้ข้าพเจ้าไม่สามารถทำกิจวัตรประจำวันดังกล่าวข้างต้น

4. ความเจ็บปวด/ความไม่สบาย
   - ☐ ข้าพเจ้าไม่มีอาการปวดหรือรู้สึกไม่สบาย
   - ☐ ข้าพเจ้ามีอาการปวดหรือรู้สึกไม่สบายปานกลาง
   - ☐ ข้าพเจ้ามีอาการปวดหรือรู้สึกไม่สบายอย่างมาก

5. ความวิตกกังวล/ความซึมเศร้า
   - ☐ ข้าพเจ้าไม่มีความวิตกกังวลหรือความซึมเศร้า
   - ☐ ข้าพเจ้ามีความวิตกกังวลหรือความซึมเศร้าปานกลาง
   - ☐ ข้าพเจ้ามีความวิตกกังวลหรือความซึมเศร้าอย่างมาก

APPENDIX C

(a) Health professional-led, small group DM-SMS

Participants

Patients aged 20 years or more who were diagnosed by physician as having type 2 diabetes of not longer than 10 years. Their latest HbA1c levels were > 7% (within the last 24 weeks), and BMI> 25 kg/m^2. They must reside in Bangkok and possess home and/or mobile telephone . Those with serious diseases, unable to do physical activity, being pregnant, or on diet were excluded from the study.

Setting:

Out-patient department of Chulalongkorn Memorial Hospital and public health centers of the Bangkok Metropolitan Administration (BMA)

Number of samples:

Eighty eight participants for the control and eighty six the experimental groups.

The intervention :

The six sessions of two-weekly small group activity which were arranged and facilitated by health professional in the healthcare facility. Each session lasted two hours, and the whole program was three months duration. Topics covered included: (1) an introduction to the program and basic knowledge about type 2 diabetes; (2) physical activity; (3) healthy diet; (4) diabetes medication; (5) coping with stress, and; (6) monitoring type 2 diabetes complications and developing the life-long problem solving skill. The control or “usual care” group is commonly given the basic diabetes knowledge performed in hospitals.

(b) Peer-led, small group DM-SMS.

Participants:

The same as in section (a).

Setting:

public health centers of the Bangkok Metropolitan Administration (BMA)

Number of samples: seventy participants each for the control and the experimental groups.

The intervention:

The six sessions of monthly small group activity which were arranged and facilitated by the peers (three for each participant group) in the healthcare facility. Peers were type 2 diabetes patients who were well controlled of their diabetes. Most of them were the members of the Diabetes Patient Club of King Chulalongkorn Memorial Hospital and had entered the 5-day training program to be the peer supporters. Each session lasted two hours, and the whole program was six months. Topics covered were the same as in section (a). However, the "diabetes medication" topic was focus only about medication adherence and coping with medication side-effects without going in detail of each medication type. The control or "usual care" group received the similar treatment as described in the section (a).

(c) Telephone-based DM-SMS.

Participants:

The same as in the section (a). Furthermore, they must possess home or mobile telephone.

Setting:

King Chulalongkorn Memorial Hospital and Ladkrabunk Hospital.

Number of samples: one hundred twelve for the control group and experimental groups.

The intervention :

The intervention was conducted via the automated phone system over the 6-month period. The system consisted of three components including (a) the suggestion interactive voice response or SG- IVR; (b) the question and answer interactive voice response or QA –IVR, and; (c) the knowledge management interactive voice response or KM- IVR. In the first 3 months each patient received automatically calls for: 1) the clinical assessment by questionnaires; 2) the provision of knowledge related to type 2 diabetes self-management, and; 3) Educator contacts with specific patient in case of the potential critical result(s) his/her from the automated phone contact. Frequencies of contact were as followed: in the first two months, twice a week to communicate

closely; in the third month, once a week to be linked to participants farther than previous ; in the last three months, once a month to make connection. The control or "usual care" group received the similar treatment as described in the section (a).

(d) internet-based DM-SMS

Participants:

The same as in the section (a). Furthermore, they must be able to access to the internet at least twice a week, to be reached via home or mobile phone. They must be willing to increase physical activity to 150 mins / wk in 6 months, keep and report a food diary.

Setting:

King Chulalongkorn Memorial Hospital and four business companies in Bangkok.

Number of samples: forty eight and seventy six respectively for the control and the experimental groups.

The intervention:

The intervention was conducted via the internet website system. There were five components of the intervention system including: (a) Self regulation and management; (b) Self-monitoring and evaluation; (c) Support knowledge and tools for behavior change; (d) Social support, and; (e) Reminder and virtual home visit. At the beginning of the program each participant was orientated about how to use the website. They were then invited to use the website for the 6-month period. They were expected to login to the website at least two times per week, and use whatever component they want. The e-mail prompt will be sent to the participant who did not log-in to the system for tracking. E-mail or telephone contact with the participants were also initiated when reporting the laboratory results as well as the relating suggestions back to them.

For the participants in the control group, the e-mails containing knowledge about type 2 diabetes self-management were sent to them once a week for up to 24 topics within 24-week period. Laboratory results and relating suggestion were also

sent to each participant via the e-mail. One pedometer was provided for each participant in both the control and experimental groups.

APPENDIX D

Value of cost variable (Bath) (1)

Items	Dose	Value	Items	Dose	Value
Medicine (DMSIC.moph.go.th/price)			**Medicine** (DMSIC.moph.go.th/price)		
Glipizide	5mg	0.23	Enaril	20mg	0.48
Glimepiride	2mg	4.3	Imidapril(Tanatril)	10mg	10
Plioglitazone	15mg	4.7	Losartan	50mg	2.03
Plioglitazone	30mg	7.57	Losartan	100mg	10.05
Metformin	500mg	0.45	Irbesartan(Aprovel)	300mg	28.79
Metformin	850 mg	1.07	Ramipril	2.5mg	6.3
Sitagliptin	100mg	49.22	Ramipril	5mg	10.37
HumulinN	3mL	125.48	Atenolol	25mg	0.26
HumulinN	10mL	140.77	Atenolol	50mg	0.25
InsulatardHM	3mL	120.85	Atenolol	100mg	0.45
Humulin70/30	3mL	118.46	Metoprolol	100mg	0.8
Humulin70/30	10mL	158.75	Amlodipine	5mg	1.01
MixtardHM30	3mL	118.46	Amlodipine	10mg	1.51
MixtardHM30	10mL	158.75	Manidipine	10mg	8.18
Humalogmix25	3mL	299.6	Manidipine	20mg	13.39
Levemir flexpen	3mL	629.26	Felodipine	5mg	5.39
Acarbose(tab)	50mg	3.32	NifedipineCR	30mg	17.06
Acarbose(tab)	100mg	5.5	Lercarnidipine	10mg	18.42
HCTZ	25mg	0.18	Co-Diovan	80/12.5	17.56
HCTZ	50 mg	0.25	Co-Diovan	160/25	22.43
Lasix	40mg	0.28	Coaprovel	300/12.5	27.46
Lasix	500mg	2	Telmisartan	40mg	17.65
Moduretic		0.36	Telmisartan	80mg	23.22
Enaril	5mg	0.2	Micardis plus	80/12.5	23

Value of cost variable (Bath) (2)

Items	Dose	Value	Items	Dose	Value
Medicine (DMSIC.moph.go.th/price)			**Laboratory**(reimbursement)		
Diltiazem CR	120mg	13.52	FBG		40
DiltiazemR	200mg	10	HbA1C		150
Doxazosin	2mg	1.97	Fructosamine		100
Doxazosin	4mg(XL)	21.4	Cholesterol (total)		60
Hydralazine	10mg	0.4	LDL		150
Hydralazine	25mg	1.5	HDL		100
Simvastatin	10mg	0.8	TG		60
Simvastatin	20mg	1.21	BUN		50
Simvastatin	40mg	1.81	Creatinine		50
Crestor(Rosuvastatin)	20mg	57.76	Albumin		50
Atorvastatin(Lipitor)	20mg	28.26	Protien(spot urine)		50
Fenofibrate	100mg	3.07	Creatinine(spot urine)		50
Fenofibrate	300mg	12.84	UA		50
			urea		
Ezetemibe	10mg	43.53	nitrogen(Blood)		50
Gemfibrozil	600mg	0.88	CBC		90
ASA	81mg	0.22	Protein		50
ASA	300mg	0.28	SGPT		50
			SGOT		50
			Alkaline		
Medical supplies (DMSIC.moph.go.th/price)			phosphatase		50
Novofine needle 30G		4.5	CPK		90
Syring insulin (30G)	50U	2.62			
Syring insulin (30G)	100U	2.65			
cottonball/pack	30 pieces	5.5			

Value of cost variable (Bath) (3) (2007 based year)

Items	Value	Adjusted value
Routine service cost (per visit)		
1. King Chulalongkorn Memorial Hospital (2001)	589.54	796.72
2. Lat Krabang hospital (2010)	537.23	570.06
3. Public health center of the Bangkok Metropolitan Administration (BMA) (2003)	361.33	475.96

1,3 : To estimate and adjust data from previous study (Pirom Kamolratanakul, et al.;"Cost analysis of patients services in King Chulalongkorn Memorial Hospital: Patients services areas. And Napassanun Limsantithum; "Cost-effectiveness analysis of chronic disease management: comparison between King Chulalongkorn Memorial Hospital and Public Health center 16 Lumpini.) including 2

APPENDIX E

Data of cost for calculating cost analysis (6 months)

Items	N	Min	Max	Median	Mean (SD)	T-Test p-value
1. Routine service cost	296	951.92	4780.31	2390.2	2325.6 (730.58)	1
2. Medical care cost						
2.1 Medicine & Medical Supplies	258	42.78	37575.1	2549.33	4382.95 (5427.92)	0.99
2.3 Laboratory	235	0	4760	1030	1119.36 (689.49)	0.98
3. Direct non-medical cost	297	0	103000	1020	2308.51(9016.30)	1

Data of outcomes for calculating cost analysis

Items	N	Min	Max	Median	Mean (SD)
Utility at third month					
1.Usual care	77	0.02	1	0.79	0.80 (0.20)
2.Health professional led	94	0.09	1	0.79	0.83 (0.17)
3.Peer led					
4.Telephone based	58	-0.12	1	0.88	0.85 (0.20)
5.Website based	16	0.22	1	1	0.87 (0.22)

APPENDIX F

Five guideline of choosing among therapies (Economic evaluation in clinical trials, Oxford)

Items	Cost or outcome analysis		cost-effectivenes analysis	
	Accept	Reject	CMA	CEA
1. Larger cost and effect ; The cost-effectiveness below maximum willing to pay.	Yes			Yes
2. Smaller cost and larger effect	Yes			
Larger cost and smaller effect		Yes		
In neither case				Yes
3. Not different in effect, adopt the therapy with the lower cost			Yes	
4. Not different in cost, adopt the therapy with the larger effect	Yes			
5. Fial to differ in both their cost and effect		Yes		

CMA = cost-minimization analysis; CEA = cost-effectiveness analysis

BIOGRAPHY

NAME	Miss Pornpan Khwakhong
DATE OF BIRTH	August 4, 1975
PLACE OF BIRTH	Bangkok, Thailand
INSITUTION ATTENDED	Faculty of pharmacy,Mahidol university,1998
	Bachelor's degree of pharmacy
	Sukhothai Thamathirah Open University, 2004
	Master of public health (Public health administration)
POSITION & OFFICE	Pharmacist of Nakhon Nayok hospital province